Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CURIA IP HOLDINGS, LLC, **Plaintiff,** **v.** **SALIX PHARMACEUTICALS, LTD., *et al.*,** **Defendants.**	**Civil Action No. 21-19293 (ES) (JRA)** **OPINION**

SALAS, DISTRICT JUDGE

Plaintiff Curia IP Holdings, LLC brought this consolidated patent infringement suit against Defendants Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Companies, Inc.; Alfasigma S.p.A.; and Alfasigma USA, Inc. (together "Defendants") (*Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-19293 & *Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 23-13764).[1] Before the Court is the parties' request for claim construction with respect to terms in U.S. Patent No. 11,739,099 (the "'099 Patent"). (D.E. No. 233 ("Pl. Open. Br."); D.E. No. 234 ("Def. Open. Br."); D.E. No. 237 ("Pl. Resp. Br."); D.E. No. 238 ("Def. Resp. Br.")). The Court held a *Markman* hearing on August 21,

[1] Plaintiff initially filed suit against Defendants on October 25, 2021. (*Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-19293 (D.E. No. 1)). The operative complaint in the original action, Civil Action Number 21-19293 (hereinafter "First Action") alleged infringement of U.S. Patent No. 9,186,355 (the "'355 Patent"), No. 10,556,915 (the "'915 Patent"), No. 10,745,415 (the "'415 Patent"), and No. 10,961,257 (the "'257 Patent"). (*Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-19293 (D.E. No. 69 ("Amended Complaint" or "Am. Compl.") ¶¶ 77–113)). The Court will hereinafter refer to the operative complaint in the First Action as the Amended Complaint. Thereafter, on August 31, 2023, Plaintiff filed another suit against Defendants (hereinafter, "Second Action") alleging infringement of U.S. Patent No. 11,739,099 (the "'099 Patent"). (*Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 23-13764 (D.E. No. 1 ("Second Complaint" or "Second Compl.") ¶¶ 72–80)). The Court will hereinafter refer to the operative complaint in the Second Action as the Second Complaint. The Second Action was consolidated with the First Action on September 27, 2023. (*Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd. et al.*, Civil Action No. 21-19293 (D.E. No. 170)). Unless otherwise noted, the Court's citations to docket entry numbers correspond to the docket entry numbers in the First Action, Civil Action Number 21-19293.

2024. (D.E. No. 246). This Opinion sets forth the Court's constructions of the disputed terms in the '099 Patent.

I. BACKGROUND

A. Technology Overview

On August 31, 2023, Plaintiff Curia IP Holdings, LLC filed a patent infringement suit against Defendants Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Companies, Inc.; Alfasigma S.p.A.; and Alfasigma USA, Inc alleging infringement of the '099 Patent. (*See* Second Compl. ¶¶ 72–80). The '099 Patent contains claims directed to tablets comprising mixtures of polymorphic forms of the antibiotic rifaximin. (*See generally* D.E. No. 234-3, Ex. 2 ("'099 Patent") to D.E. No. 234-1 ("Weisbruch Decl.")).

Rifaximin is an antibiotic with a low gastrointestinal ("GI") absorption. ('099 Patent at 1:26–60). Because it is poorly absorbed into the bloodstream, rifaximin acts locally in the GI tract and can be used in therapy for the treatment of GI infections such as traveler's diarrhea and hepatic encephalopathy. (*Id.*). Like other active pharmaceutical ingredients ("APIs"), rifaximin can exist in numerous crystalline forms, referred to as polymorphs. (*See, e.g.*, '099 Patent at 1:61–2:3; D.E. No. 233-1 ("Swift Decl.") ¶ 61). While polymorphs share the same chemical composition, they possess different three-dimensional packing arrangements based on the configuration of individual molecules within their crystal structure. (Swift Decl. ¶ 43). Different polymorphs can exhibit different properties—including chemical and physical stability—because of their distinct three-dimensional packing arrangements. (*Id.* ¶ 45). These different properties are significant to pharmaceutical manufacturers because they can affect the handling properties and ease with which a drug can be formulated, as well as the stability and bioavailability of the drug product. (*Id.*). In fact, the U.S. Food and Drug Administration ("FDA") has emphasized that "polymorphism can

affect the quality, safety, and efficacy of [a] drug product" and "issues relating to polymorphic forms may be relevant to new drug applications." (*Id.*). The specification of the '099 Patent identifies at least the following polymorphic forms of rifaximin: α, β, γ, ε, δ, ζ, η, α dry, κ, and θ. ('099 Patent at 1:60–2:3).

Because different polymorphic forms of an API exhibit different chemical and physical properties, pharmaceutical manufacturers often wish to characterize the crystalline form(s) of an API to determine its structure and physical properties. (Swift Decl. ¶ 48). X-ray diffraction ("XRD" or "DRX") is the primary analytic technique for characterizing the structure of crystalline forms of APIs. (*Id.*). XRD experiments can be carried out on single crystals or on polycrystalline powdered samples. (*Id.* ¶ 52). When performed on powders, this technique is known as X-ray powder diffraction ("XRPD"). (*Id.* ¶ 53). XRPD is performed by exposing a crystalline powder sample to X-rays of a certain wavelength. (*Id.* ¶ 51). When X-rays are directed at a crystalline sample, they are diffracted by the atoms contained within the sample at a unique set of "scattering angles" which differ in their intensities based on the type and arrangements of atoms and molecules in the sample. (*Id.* ¶¶ 51–52). An instrument known as an X-ray diffractometer measures the intensity of the X-rays that diffract across a range of angles. (*Id.* ¶ 49). The output of an XRPD experiment is typically reported as a graphical pattern known as a diffractogram, where the x-axis plots the scattering angle of the diffracted X-ray beam in terms of 2θ ("two theta" or "2theta") given in units of degrees, and the y-axis plots the intensity of the diffracted X-ray beam either in absolute units, or relative units as compared to the most intense peak in the diffractogram. (*Id.* ¶ 54). A sample diffractogram taken from the '099 Patent is reproduced below.

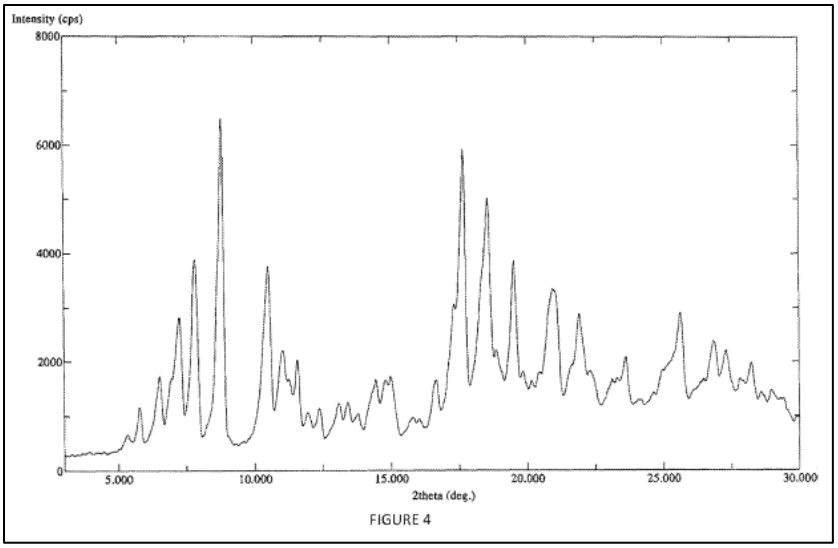

FIGURE 4

('099 Patent at Figure 4). Each crystalline compound has a unique diffraction pattern, analogous to a "fingerprint." (Swift Decl. ¶ 56 (citing D.E. No. 233-12, Ex. K. ("USP 941") to Swift Decl.)). And the diffraction pattern of an unknown sample can be compared to other samples or standard reference patterns of known compounds, to identify the sample. (*Id.* ¶¶ 49–50 & 56).

B. The '099 Patent

The '099 Patent is entitled "Polymorphic Mixture of Rifaximin and its Use for the Preparation of Solid Formulations" and discloses a "Rifaximin polymorphic mixture of α/β form" that exists in a specific ratio, namely "in a relative ratio of 85/15±3 and a process for its preparation." ('099 Patent at Abstract). The claimed polymorphic α/β rifaximin mixtures in the '099 Patent are also characterized by X-ray diffraction with certain characteristic XRPD 2theta scattering angle values. (*See id.* at 11:1–10). The '099 Patent is part of the same patent family as three other patents that were previously at issue in this case. Those patents include the '915 Patent, the '415 Patent, and the '257 Patent" (together with the '099 Patent "the '915 Patent Family"), which are also entitled "Polymorphic Mixture of Rifaximin and its Use for the Preparation of Solid Formulations" and each disclose a "Rifaximin polymorphic mixture of α/β form" that exists in a specific ratio, namely "in a relative ratio of 85/15±3 and a process for its preparation." (D.E. No.

234-4, Ex. 3 ("'915 Patent") to Weisbruch Decl. at Abstract; D.E. No. 234-6, Ex. 5 ("'257 Patent") to Weisbruch Decl. at Abstract; D.E. No. 234-5, Ex. 4 ("'415 Patent") to Weisbruch Decl. at Abstract). While the '915 and '257 Patents are directed to rifaximin mixtures and pharmaceutical compositions comprising the same mixtures, the '415 Patent is directed to methods of treatment for administering those rifaximin mixtures and pharmaceutical compositions. (*See, e.g.*, '915 Patent at 10:50–57; '257 Patent at 10:66–11:3; '415 Patent at 10:64–11:9). The '099 Patent shares a common specification with the '915 Patent, '257 Patent, and '415 Patent.[2]

Claim 1 of the '099 Patent is currently at issue and reads as follows:

> 1: A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('099 Patent at 11:1–10). The parties dispute the proper construction of the following two claim terms:

> "[A] Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" ('099 Patent, Claim 1)
>
> "[C]haracterized by an X-Ray spectrum with characteristic 2theta values" ('099 Patent, Claim 1)

(*See* Pl. Open Br. at 9 & 18; Def. Open. Br. at 1).

C. This Court's Prior *Markman* Decision

This is the second round of claim construction in this matter. In the first round of claim construction, the Court construed claims of the four patents asserted in the First Action including

[2] The '915 Patent is the parent patent in the family, the '415 Patent is a divisional of the '915 Patent, the '257 Patent is a continuation of the '915 Patent, and the '099 Patent is a divisional of the '257 Patent. (*See* '415 Patent Face Page; '257 Patent Face Page; '099 Patent Face Page).

the ’355 Patent as well as the ’915 Patent, ’257 Patent, and ’415 Patent, which as described above, are in the same patent family as the ’099 Patent now at issue.[3] The Court held a *Markman* hearing to address the proper construction of terms in the ’355 Patent, ’915 Patent, ’257 Patent, and ’415 Patent (D.E. No. 135), and issued an Opinion and Order construing terms in those patents. (D.E. Nos. 210 & 211).

One of the terms the Court construed that appeared in both the ’915 Patent and ’257 Patent was “[a] rifaximin polymorphic mixture of α/β form.” (D.E. No. 210 (“*Markman* Opinion I”) at 45 (citing ’915 Patent at 10:50–57 & ’257 Patent at 10:66–11:3)). While Plaintiff argued that the context of the claim language and the intrinsic record supported a construction of “[a] rifaximin polymorphic mixture of α/β form” that encompassed “any Rifaximin polymorphic mixture comprising both the α and β forms of Rifaximin” including mixtures with other polymorphic forms of rifaximin in addition to the α and β forms, Defendants argued that the claim language and intrinsic record supported a construction of “[a] rifaximin polymorphic mixture of α/β form,” which contained no other rifaximin polymorphs. (*Id.* at 46 (citing D.E. No. 80 at 18–23 & D.E. No. 79 at 20–24)). In other words, the parties’ dispute centered around whether “[a] rifaximin polymorphic mixture of α/β form” encompassed rifaximin polymorphs other than the α and β forms. (*Id.*). After reviewing the intrinsic evidence, including the claim language, specifications of the ’915 Patent and ’257 Patent, and the prosecution history of the ’915 Patent, the Court adopted Defendants’ construction and construed “[a] rifaximin polymorphic mixture of α/β form” to mean “[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs.” (*Markman* Opinion I at 45 & 62).

[3] The ’355 Patent is in a distinct patent family from the ’915 Patent, ’415 Patent, ’257 Patent, and ’099 Patent and has its own distinct patent specification. (*See* D.E. No. 233-18).

In construing that term, the Court began by noting that the claim language left open the possibility that "[a] rifaximin polymorphic mixture of α/β form" may encompass additional rifaximin polymorphs because the disputed claim term used the phrase "mixture" before "α/β form," which the Federal Circuit has held does not bar additional, unnamed ingredients. (*Id.* at 46–47 (citing *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004)). Nevertheless, though the claim language, standing on its own, left open the possibility that the disputed term may encompass additional rifaximin polymorphs, the Court found that the claim language, when read in view of the specifications, indicated that the proper construction of "[a] rifaximin polymorphic mixture of α/β form" is one that contains no other rifaximin polymorphs. (*Id.* at 46). The Court held that "the specifications of the '915 Patent and '257 Patent are affirmatively limiting," and "preclude [the] possibility" that other rifaximin polymorphs could be present. (*Id.* at 53–54). In reaching this conclusion the Court explained that the passages of the specifications in the '915 Patent and '257 Patent—which (i) explained that the conversion between polymorphic forms of rifaximin was a problem in the prior art, (ii) repeatedly emphasized that it is critical to guarantee the consistency of crystalline forms, (iii) disparaged prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*" of rifaximin, and (iv) attributed the "surprising[]" properties of the inventions to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*—indicated that Claim 1 of the '915 Patent and Claim 1 of the '257 Patent do not encompass polymorphs other than the desired and consistently produced α/β forms in a specific ratio. (*Id.* at 51 (citing '915 Patent at 2:9–17, 18–23, 33–44 & 64–67 (emphasis added) and '257 Patent at 2:13–22, 23–28, 40–51 & 3:3–6) (emphasis added))). The Court's conclusion was reinforced by the fact that each figure and example in the specifications of the '915 Patent and

'257 Patent that depicted or disclosed a "[a] rifaximin polymorphic mixture of α/β form," showed mixtures that contained only the α and β forms of rifaximin, further indicating that Claim 1 of the '915 Patent and Claim 1 of the '257 Patent do not encompass polymorphs other than the desired and consistently produced α/β forms of rifaximin. (*Id.* at 52 (citing'915 Patent at 8:43–10:47 & '257 Patent at 8:52–10:64)).

In addition, the Court found that the prosecution history of the '915 Patent supported Defendants' construction. (*Id.* at 54–55). The Court noted that during prosecution of the '915 Patent, the applicant again emphasized the importance of the consistency of the polymorphic form and criticized prior art methods that "produced the undesired γ polymorphic form or other polymorphic mixtures" of rifaximin. (*Id.* at 55 (citing D.E. No. 79-7, Ex. 6 ("'915 Patent File History") to D.E. No. 79-1 at 3–4)).[4] Further, at multiple points during prosecution, when distinguishing the present invention over U.S. Patent Number 8,067,429 to Gushurst to overcome an obviousness rejection, the applicant of the '915 Patent emphasized that it was the "specific ratio of α/β" claimed by the patent that "produced unexpected stability during physical treatments employed for the dry granulation and tableting." (*Id.* (citing '915 Patent File History at 5 & 34)). The applicant contrasted this to "[o]ther known polymorphs of rifaximin" that "may easily change their polymorphic form if exposed to different values of relative humidity." (*Id.*). Accordingly, the Court found that the applicants' statements during prosecution—which emphasized the importance of the consistency of the polymorphic form and underscored that it was the specific ratio of α to β claimed by the invention that produced unexpected stability in contrast to other

[4] Unless otherwise noted, pin cites to Docket Entry Number 79-7 refer to the pagination automatically generated by the Court's electronic filing system. Because the '915 Patent is in the same family as the '257 Patent and is its parent, the Court found the prosecution history of the '915 Patent relevant in interpreting the same disputed claim term in the '257 Patent. (*Markman* Opinion I at 54–55 n.13 (citing *Capital Mach. Co. v. Miller Veneers, Inc.*, 524 F. App'x 644, 649 (Fed. Cir. 2013) (stating "that the prosecution history regarding a claim term is pertinent when interpreting the same term in both later-issued and earlier-issued patents in the same family"))).

known polymorphs of rifaximin that could easily change their polymorphic form—indicated that the applicant intended to limit the claims to only the consistently produced α/β mixture, which did not contain any other undesired rifaximin polymorphs. (*Id.*). As such, after considering claim context, the specifications, and the prosecution history of the '915 Patent, the Court adopted Defendants' construction and construed "[a] rifaximin polymorphic mixture of α/β form" in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent to mean "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs." (*Id.* at 62).

The Court applied the same analysis to other claim terms in the '915 Patent, '257 Patent, and '415 Patent that were likewise directed to rifaximin polymorphic mixtures of α/β form. (*See id.* at 62–64 (construing "[a] pharmaceutical composition" as appearing in the '915 Patent, Claim 2 and '257 Patent, Claim 2 to mean "[a] pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1); *id.* at 64–66 (construing "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" as appearing in the '915 Patent, Claim 3 and '257 Patent, Claim 10 to mean "[a] tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1); *id.* at 66–70 (construing "a pharmaceutical composition" as appearing in the '415 Patent, Claims 1 and 9 to mean "a pharmaceutical composition comprising rifaximin in an α/β polymorphic mixture and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257

Patent, Claim 1 because the '415 Patent shares a common specification with the '915 Patent and '257 Patent); *id.* at 70–72 (construing "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" as appearing in the '415 Patent, Claims 4 and 12 to mean "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs" based on the same intrinsic record the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1 because the '415 Patent shares a common specification with the '915 Patent and '257 Patent)).[5]

The Court also construed a term in the '915 Patent which read as follows: "characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)" and a similar term in the '415 Patent and '257 Patent that read: "characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92." (*Markman* Opinion I at 72 & 113). While Plaintiff argued that the intrinsic and extrinsic record supported a construction of the disputed claim terms that meant characterized by an X-Ray spectrum with characteristic values at *about* the claimed 2theta values and relative intensity values, Defendants argued that each of the 2theta values and relative intensity values in the disputed claim terms should be interpreted as exact, potentially subject to rounding. (*Id.* at 72–73 & 113–14). In other words, the parties' dispute centered around whether each of the recited 2theta values and relative intensity values in the claims should be construed as "about" or absolute.

[5] In construing terms of the '415 Patent in this manner, the Court also considered the prosecution history of the '915 Patent—a member of the same patent family. (*Markman* Opinion I at 69 n.15 (citing *Capital Mach. Co.*, 524 F. App'x at 649)).

(*Id.*). After considering the intrinsic and extrinsic evidence, the Court construed the recited 2theta values and relative intensity values as "about," even though the claims at issue did not explicitly recite the term "about" in modifying the recited values. (*See id.* at 73–118). Relevant to the Court's conclusion was the fact that the specifications of the '915 Patent, '257 Patent, and '415 Patent explicitly provided that it was to be understood that all values and intervals disclosed in the process of the present inventions must not be intended as absolute but rather should be understood as about. (*Id.* at 74–75 & 115–16). Further, certain figures in the specifications of the '915 Patent, '257 Patent, and '415 Patent indicated that the recited values exhibited some variability and thus should be construed as "about." (*Id.* at 77–83 & 116–17). In addition, the Court found that extrinsic evidence, which was consistent with the intrinsic record, indicated that the recited values should be understood as "about" because it was well recognized that X-ray diffraction and the measurement of 2theta values and relative intensity values involved variability. (*Id.* at 83–85, 104–05 & 117–18).

II. LEGAL STANDARD

The ultimate question of the proper construction of a patent is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388–91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* (citation omitted).

The words of a claim are generally given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id*. at 1313. To determine the ordinary and customary meaning of a disputed term, the court must look to "those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Id.* at 1314. (internal quotation marks and citation omitted). Thus, the court must "look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence." *Meyer Intellectual Props. Ltd. v. Bodum, Inc*., 690 F.3d 1354, 1368 (Fed. Cir. 2012) (citation omitted); *see also Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (*e.g.*, the patent specification and file history) and extrinsic evidence (*e.g.*, expert testimony).").

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314 (citations omitted). Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.* (citation omitted).

"The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument,' consisting principally of a specification that concludes with the claims." *Id.* at 1315 (internal citations omitted). As such, the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Indeed, "the specification necessarily informs the

proper construction of the claims" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316–17. Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Specifically, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323. Nevertheless, "the specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316; *see also Aventis Pharm. Inc. v. Amino Chems. Ltd*., 715 F.3d 1363, 1373 (Fed. Cir. 2013) ("The written description and other parts of the specification, for example, may shed contextual light on the plain and ordinary meaning; however, they cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope."). "Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (internal quotation marks and citation omitted).

The court should also consider the patent's prosecution history—"the complete record of the proceedings before the [Patent and Trademark Office] . . . includ[ing] the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor

understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Finally, in some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318–19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

III. DISCUSSION

A. Person of Ordinary Skill in the Art

Claims are construed from the vantage point of a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips*, 415 F.3d at 1313. Thus, before a court can review the disputed claim terms and phrases, it must determine "the level of skill that a POSA possessed

at the time of the invention." *Cambria Co. LLC v. Hirsch Glass Corp.*, No. 21-10092, 2022 WL 4031422, at *3 (D.N.J. Sept. 2, 2022).

Here, the parties define a POSA similarly. According to Plaintiff's expert, Dr. Swift,

> the POSA for the patents-at-issue, including the '099 [P]atent, is a scientist with a degree in pharmaceutical science, chemistry, or chemical engineering, and/or materials sciences with the working knowledge of the theory and practice of crystallography, crystal engineering, and pharmaceutical solid state chemistry, including polymorph, salt, and/or co-crystal screening, characterization, and development. The POSA could have a Ph.D. or Master's degree, but a Bachelor's degree in these disciplines coupled with at least five years of practical experience in the field of pharmaceutical solid state chemistry is also sufficient. The POSA may also work in collaboration with other individuals who have experience in pharmaceutical formulation and/or medicinal chemistry, as well as in developing pharmaceutical drug products.

(Swift Decl. ¶ 31; Pl. Open. Br. at 5–6). While similar to Plaintiff's definition, Defendants propose a distinct definition of a POSA that includes a multi-disciplinary team. According to Defendants:

> A person of ordinary skill in the art would have been a multi–disciplinary team including: (1) a person who would have had a Ph.D. in chemistry, chemical engineering, or a related discipline, with a minimum of three years' experience related to powder x–ray diffraction analysis of solid active pharmaceutical ingredients ("API") and/or drug products, along with other forms of characterization, testing, and/or evaluation of API and/or drug products; (2) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, or a related discipline with knowledge and/or experience related to the manufacture of solid active pharmaceutical ingredients and the manufacture of drug products; (3) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, biology, molecular biology, or a related discipline with knowledge and/or experience with respect to solid polymorphic forms of chemical compounds, specifically including rifaximin, along with their characterization, testing, properties, and *in vivo* operation; and (4) a person that would have had (i) a Ph.D. in pharmacology, biology, molecular biology, biomedical science, microbiology, or a related discipline, and/or (ii) a medical degree and board certification in gastroenterology. For each of these disciplines, a POSA team member could have a

> bachelor's and/or master's degree along with longer relevant experience.

(Def. Open. Br. at 5–6). Though the POSA definitions set forth by the parties differ, there is no suggestion that the differences will impact the Court's construction of the disputed claim terms. And the parties have made no argument to suggest that any distinction between their proposed definitions would have any impact on the outcome of this claim construction. (*See generally* Pl. Open. Br.; Def. Open. Br.; Pl. Resp. Br. & Def. Resp. Br.). As such, the Court sees no material difference between the definitions put forth by the parties and finds that its claim construction analyses would be the same under either definition. *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 265 F. Supp. 3d 490, 496–97 (D.N.J. 2017), *aff'd*, 747 F. App'x 852 (Fed. Cir. 2018).[6]

B. Construction of Disputed Terms

The Court sets forth the construction of the disputed claim terms below.

a. Disputed Claim Terms in the '099 Patent

1. "[A] Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" ('099 Patent, Claim 1)

Plaintiff	Defendants	The Court
Construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin	"A rifaximin polymorphic mixture that comprises α and β Rifaximin	"A rifaximin polymorphic mixture that comprises α and β Rifaximin

[6] In its responsive brief, Plaintiff points out that Defendants have proposed a definition of a POSA during this round of claim construction that differs from the definition of a POSA they set forth in the initial round of claim construction in this case. (Pl. Resp. Br. at 19–20). Specifically, unlike the definition of a POSA that Defendants had previously proposed, Defendants now seek to alter their definition of a POSA to include that "[f]or each of these disciplines, a POSA team member could have a bachelor's and/or master's degree along with longer relevant experience." (*Id.* at 20). Plaintiff points out that this "is the very same addition that Defendants are attempting to add to their invalidity contentions, to which [Plaintiff] has objected." (*Id.*). And Plaintiff notes that the Honorable Jose R. Almonte, U.S.M.J., issued an order in response to Defendants' motion to amend their invalidity contentions stating that it "will hold [Defendants'] motion" "in abeyance pending the Court's decision of Defendants' renewed Motion for Judgment on the Pleadings. (*Id.* (citing D.E. No. 229)). Plaintiff asserts that Defendants should not be permitted to use claim construction as a means to circumvent Judge Almonte's order. (*Id.*). Nevertheless, at the *Markman* hearing, Plaintiff conceded that this Court's claim construction analysis should not differ under any of the proposed definitions of a POSA that the parties have put forth in this case. (D.E. No. 250 ("*Markman* Hr'g Tr.") at 6:7–16). As such, the Court need not resolve any dispute regarding Defendants' alteration to their proposed definition of a POSA at this time.

polymorphs" is not necessary. To the extent construction is necessary, "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" is meant to have its plain and ordinary meaning, *e.g.*, "any Rifaximin polymorphic mixture that comprises both the α and β forms of Rifaximin." The term "comprises" is open ended and its plain and ordinary meaning allows for inclusion of other rifaximin polymorphs.	polymorphs and no other Rifaximin polymorphs"	polymorphs and no other Rifaximin polymorphs"

The disputed claim term "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" appears in Claim 1 of the '099 Patent which reads as follows:

> 1: A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('099 Patent at 11:1–10). Plaintiff argues that the context of the claim language and the intrinsic record support a construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" that encompasses "any Rifaximin polymorphic mixture that comprises both the α and β forms of Rifaximin" including mixtures with other polymorphic forms of rifaximin in addition to the α and β forms. (Pl. Open. Br. at 9–17). Defendants contend that the Court's decision in *Markman* Opinion I governs the construction of this disputed claim term. (Def. Open. Br. at 2). Specifically, Defendants point out that in *Markman* Opinion I, the Court ruled that the common specifications of the '915 Patent, '257 Patent, and '415 Patent—which are in the same patent family as the '099 Patent—limited the construction of similar open-ended terms claiming rifaximin mixtures to rifaximin polymorphic mixtures which contain α and β rifaximin

polymorphs and no other rifaximin polymorphs. (*Id.* at 2 & 7; *Markman* Opinion I at 45–72). Because the specification of the '099 Patent is substantively identical to the specifications of the '915 Patent, '257 Patent, and '415 Patent, Defendants contend that consistent with *Markman* Opinion I, "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs," should be construed to mean "[a] rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs." (Def. Open. Br. at 6–7). Accordingly, the parties dispute centers around whether "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" encompasses rifaximin polymorphs other than the α and β forms. For the reasons set forth below, the Court adopts Defendants' construction.[7]

i. The Intrinsic Record Supports Defendants' Construction

In resolving the parties' disputes, the Court begins, as it must, with the words of the claims. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). Here, as Plaintiff points out (Pl. Open. Br. at 11–12), Claim 1 of the '099 Patent in which the disputed claim term appears uses the transitional phrase "comprising" before describing the claimed polymorphic mixture, and also uses the transitional term "comprises" before defining the polymorphs that are encompassed by the claimed rifaximin mixture ('099 Patent at 11:1–10), which are terms of art in patent law that mean "including" or "including but not limited to." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009) ("The claim uses the term 'comprising,' which is well understood in patent law to mean 'including but not limited to.'"). Further, Claim 1 of the

[7] In their opening brief, Defendants contend that *Markman* Opinion I is law of the case and compels the conclusion that "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" should be construed to mean "[a] rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs." (Def. Open. Br. at 6–7). In its responsive brief, Plaintiff contends that the law of the case doctrine should not control because Claim 1 of the '099 Patent contains significantly different claim language from the claim language that was before the Court in *Markman* Opinion I. (Pl. Resp. Br. at 8). The court need not resolve this issue because, as discussed below, here the intrinsic record of the '099 Patent compels the conclusion that "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" should be construed to mean "[a] rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs."

'099 Patent uses the phrase "mixture" when describing the claimed rifaximin composition ('099 Patent at 11:1–10), which the Federal Circuit has held "does not exclude additional, unnamed ingredients." *Mars*, 377 F.3d at 1376; (Pl. Open. Br. at 12–13). It is true, of course, that open-ended terms like "comprising," "comprises," and "mixture" signal "that the body of the claim is open." *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001); *Mars*, 377 F.3d at 1376. However, the "determination of what is or is not excluded by a transitional phrase must be made on a case-by-case basis in light of the facts of each case" Manual of Patent Examining Procedure ("MPEP") § 2111.03, and the use of open-ended terms such as "comprising," "comprises," and "mixture" do not displace, "or otherwise allow one to disregard, the patent specification." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 672 (Fed. Cir. 2018). "[C]laims . . . do not have meaning removed from the context from which they arose." *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001). As such, the claims must be read in view of the specification, which "is always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." *Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1355 (Fed. Cir. 2016) (quoting *Phillips*, 415 F.3d at 1315). This fundamental precept is no less true for claims with open-ended terms such as "comprising," "comprises," and "mixture" than it is for other types of claims. *Raytheon Co.*, 727 F. App'x at 672; *see also In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010) (stating that the Board's construction of a claim reciting a "comprising" limitation must be "*consistent with the specification*" (internal quotation marks omitted)); *Sequoia Tech., LLC v. Dell, Inc.*, 66 F.4th 1317, 1324 (Fed. Cir. 2023) ("In short, the use of a term denoting a non-exhaustive list does not eviscerate our obligation to construe terms in the context of the entire patent."). In fact, in *Markman* Opinion I, though the Court found that the claim language of similar terms in Claim 1 of the '915 Patent and Claim 1 of

the ’257 Patent which read “[a] rifaximin polymorphic mixture of α/β form,” left open the possibility that the disputed terms may encompass additional rifaximin polymorphs based on the use of the open-ended term “mixture,” the Court found that the claim language, when read in view of the specifications of the ’915 Patent and ’257 Patent, indicated that the proper construction of “[a] rifaximin polymorphic mixture of α/β form” is one that contains no other rifaximin polymorphs. (*Markman* Opinion I at 46–49; *see also id.* at 70–72 (construing “the pharmaceutical composition *comprises* 550 mg of Rifaximin α/β polymorphic *mixture*” as appearing in the ’415 Patent, Claims 4 and 12 to mean “the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs” based on the same intrinsic record the Court found relevant in construing “[a] rifaximin polymorphic mixture of α/β form” as appearing in the ’915 Patent, Claim 1 and ’257 Patent, Claim 1 because the ’415 Patent shares a common specification with the ’915 Patent and ’257 Patent)). Similarly here, though Claim 1 of the ’099 Patent in which the disputed claim term appears uses the terms “comprising,” “comprises,” and “mixture” when defining the claimed rifaximin composition—thereby leaving open the possibility that the claimed rifaximin mixture can encompass rifaximin polymorphs other than the α and β forms—the use of those open-ended terms does not allow this Court to disregard the patent specification when construing the disputed claim term. And as will be discussed below, here the specification of the ’099 Patent indicates that the proper construction of “a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs,” is one that contains no other rifaximin polymorphs.

“It is axiomatic that the claim construction process entails more than viewing the claim language in isolation.” *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011). As such, Claim 1 of the ’099 Patent must be read in view of the written

description. *Phillips*, 415 F.3d at 1315. In *Markman* Opinion I, the Court held that the proper construction of similar claim terms in the '915 Patent and '257 Patent which read "[a] rifaximin polymorphic mixture of α/β form" is one that contains no other rifaximin polymorphs because "the specifications of the '915 Patent and '257 Patent are affirmatively limiting," and "preclude [the] possibility" that other rifaximin polymorphs could be present. (*Markman* Opinion I at 53–54). The Court applied the same analysis to other claim terms in the '915 Patent, '257 Patent, and '415 Patent that were likewise directed to rifaximin polymorphic mixtures of α/β form. (*See id.* at 62–64 (construing "[a] pharmaceutical composition" as appearing in the '915 Patent, Claim 2 and '257 Patent, Claim 2 to mean "[a] pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1); *id.* at 64–66 (construing "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" as appearing in the '915 Patent, Claim 3 and '257 Patent, Claim 10 to mean "[a] tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1); *id.* at 66–70 (construing "a pharmaceutical composition" as appearing in the '415 Patent, Claims 1 and 9 to mean "a pharmaceutical composition comprising rifaximin in an α/β polymorphic mixture and no other rifaximin polymorphs" based on the same intrinsic evidence the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1 because the '415 Patent shares a common specification with the '915 Patent and '257 Patent); *id.* at 70–72 (construing "the pharmaceutical composition comprises 550 mg of

Rifaximin α/β polymorphic mixture" as appearing in the '415 Patent, Claims 4 and 12 to mean "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs" based on the same intrinsic record the Court found relevant in construing "[a] rifaximin polymorphic mixture of α/β form" as appearing in the '915 Patent, Claim 1 and '257 Patent, Claim 1 because the '415 Patent shares a common specification with the '915 Patent and '257 Patent)). Since the specification of the '099 Patent is substantively identical to the specifications of the '915 Patent, '257 Patent, and '415 Patent, the same conclusion is warranted here with respect to the construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" in Claim 1 of the '099 Patent.

On the one hand, the specification of the '099 Patent does use the term "mixture" when referring to the claimed invention, which leaves open the possibility that "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" may encompass additional unnamed ingredients such as rifaximin polymorphs other than α and β. (*See, e.g.*, '099 Patent at 3:1–11). However, the remainder of the specification undercuts any such possibility. To start, in describing the background of the invention, the specification of the '099 Patent explains that the conversion between polymorphic forms of rifaximin was a problem in the prior art. More specifically, the specification explains that the prior art indicates that "polymorphic forms of Rifaximin may easily change their polymorphic form if exposed to different values of relative humidity." (*Id.* at 2:14–17). Nevertheless, the specification emphasizes that this conversion between polymorphic forms of rifaximin was a problem because "in particular the crystallization and drying conditions" described in the prior art "did not consistently afford the *desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." (*Id.* at 2:23–28 (emphasis added)). The specification then emphasizes that the conversion of polymorphic

forms of rifaximin from one form to another is "critical" and needs to be taken into account to guarantee the "consistency" or "reproducibility" of the polymorphic form, because of regulatory requirements in the drug industry and because different crystal forms of rifaximin can exhibit significantly different pharmaceutical properties. (*Id.* at 2:4–22 & 40–51). In fact, the specification notes that "for the preparation of the drug product the *stability* of the polymorphic forms of Rifaximin (for example film coated tablets) is *critical*." (*Id.* at 2:52–54 (emphasis added)).

Accordingly, because the conversion of one polymorphic form of rifaximin to another was considered problematic in guaranteeing the "consistency" of the crystalline form, the specifications state that there was a need to put "appropriate manufacturing procedures in place to *consistently* yield Rifaximin *of the appropriate solid state* suitable to minimize changes of the solid state during the preparation of the drug product." (*Id.* at 2:40–67 (emphasis added)). The inventors then go on to describe how their invention overcomes these problems in the prior art, stating in the summary of the invention that "[i]t has now *surprisingly* been found that a new Rifaximin form, consisting of α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*[,] solving the problems of the prior art as discussed above," that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." (*Id.* at 2: 23–28 & 3:3–6 (emphasis added)). The specification also explains that the invention has "found a process for the preparation of a *consistent* Rifaximin α/β mixture in a relative ratio of 85/15±3 by crystallization and drying of a new polymorphic form of Rifaximin." (*Id.* at 3:7–13 (emphasis added)). As such, the specification states that "it is an object of the present invention" to produce "a Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3." (*Id.* at 3:24–26).

These passages of the specification—which (i) explain that the conversion between polymorphic forms of rifaximin was a problem in the prior art, (ii) repeatedly emphasize that it is *critical* to guarantee the *consistency* and *reproducibility* of the rifaximin polymorphic form because of regulatory requirements in the drug industry and because different crystal forms of rifaximin exhibit significantly different pharmaceutical properties, (iii) disparage prior art processes that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*," and (iv) attribute the "surprising[]" properties of the invention to the fact that an α/β rifaximin mixture in a relative ratio of 85/15±3 can be prepared *consistently*—indicate that Claim 1 of the '099 Patent does not encompass polymorphs other than the *desired* and *consistently* produced α/β forms of rifaximin in a specific ratio. (*Id.* at 2:13–67 & 3:3–13) (emphasis added)). This conclusion is further supported by the fact that the summary of the invention states that "[i]t has now *surprisingly* been found that a new Rifaximin form, *consisting* of α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*[,] solving the problems of the prior art as discussed above," that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." (*Id.* at 2: 23–28 & 3:3–6 (emphasis added)).

In addition, each figure and example in the '099 Patent that depicts or discloses "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs," only shows mixtures that contain the α and β polymorphic forms of rifaximin, indicating that Claim 1 of the '099 Patent does not encompass polymorphs other than the *desired* and *consistently* produced α/β forms of rifaximin. (*See, e.g., id.* at 8:50–10:62). In fact, where each example in the asserted patent aligns with a particular construction, as is the case here, such examples offer further support for that particular construction. *See, e.g., Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*,

808 F.3d 1313, 1317 (Fed. Cir. 2015) (affirming district court's construction in part because the "construction [wa]s supported by . . . every figure" and "patent drawings are highly relevant in construing the limitations of the claims"); *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1321 (Fed. Cir. 2016) ("Indeed, the written description offers no other suggestion as to how the recess and taper should be located to satisfy the claim language. Thus, every description and every figure in the patent that discusses the issue places the recess 'essentially midway' along the taper."); *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1019, 1028 n.3 (Fed. Cir. 2009) (limiting the term "wound" to "skin wound," rather than allowing it to encompass "pus pockets," where all of the examples in the specification involved skin wounds, even though the specification provided that those examples were for illustrative purposes only and were not to be taken as limiting). As such, though the specification of the '099 Patent does use the term "mixture," the Court finds that the use of this term cannot, on its own, support Plaintiff's open-ended construction. Rather, together, the statements in the specification recounted above support a construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs," which contains no other rifaximin polymorphs.

Plaintiff contends that Defendants' construction improperly adds a negative limitation into Claim 1 of the '099 Patent that can only be supported by a clear and unmistakable disavowal, which is absent here. (Pl. Open. Br. at 15–17). In fact, Plaintiff argues that Defendants' proposed claim construction would vitiate the patentees' use of open-ended terms such as "comprising," "comprises," and "mixture." (*Id.* at 16). Plaintiff contends that the facially clear meaning of this open-ended claim language cannot be changed by reliance on the specification. (Pl. Resp. Br. at 6 (citing *Straight Path IP Group, Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360–61 (Fed. Cir. 2015)). Plaintiff's arguments do not lead this Court to reach a contrary conclusion. As the Federal

Circuit has held, "a claim term may be clearly redefined without an explicit statement of redefinition" and "[e]ven when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1321 (internal quotation marks and citations omitted). In fact, "[o]ne of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case," and that "[m]uch of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention . . . or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." *Id.* at 1323. Although claims need not be limited to the preferred embodiment when the invention is more broadly described, "neither do the claims enlarge what is patented beyond what the inventor has described as the invention." *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1355 (Fed. Cir. 2006) (internal quotation marks and citation omitted)). Accordingly, "[w]hen the scope of the invention is clearly stated in the specification, and is described as the advantage and distinction of the invention," as is the case here, "it is not necessary to disavow explicitly a different scope." *Trs. of Columbia Univ. in City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir. 2016) (quoting *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006)). That is, Federal Circuit case law "does not require explicit redefinition or disavowal" when the written description itself is affirmatively limiting. *Cave Consulting Grp., LLC v. OptumInsight, Inc.*, 725 F. App'x 988, 995 (Fed. Cir. 2018) (quoting *Symantec Corp.*, 811 F.3d at 1363).

As the Court concluded in *Markman* Opinion I with respect to the specifications of the '915 Patent, '257 Patent, and '415 Patent, here the specification of '099 Patent—which is

substantively identical to the specifications of the '915 Patent, '257 Patent, and '415 Patent—is affirmatively limiting. The Federal Circuit's decision in *Retractable Technologies, Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296 (Fed. Cir. 2011) is instructive on this point. In *Retractable*, the Federal Circuit construed the term "body" in a claim covering medical syringes to mean a one-piece rather than a multi-piece body even where the claim language left open the possibility that the recited "body" could encompass a syringe body composed of more than one piece. *Retractable Techs.*, 653 F.3d at 1304–05. Relevant to the court's conclusion was that (i) the specifications distinguished prior art syringes for failing to recognize a syringe that could be molded as a one-piece body; (ii) the summary of the invention stated that the syringe featured a one-piece hollow body; (iii) the specifications, in describing the invention, expressly stated that each syringe embodiment contained a one-piece body; (iv) each figure depicted a syringe body with a one-piece body; and (v) the specifications did not disclose a body that consisted of multiple pieces or indicate that the body is anything other than a one-piece body. *Id.* at 1305. While the Federal Circuit acknowledged that there was a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims, the court found that a construction of "body" that limited the term to a one-piece body was "required to tether the claims to what the specifications indicate[d] the inventor actually invented." *Id.*

Here, the Court finds the present facts analogous. Like in *Retractable*, the specification of the '099 Patent (i) underscores that the conversion between polymorphic forms of rifaximin was a problem in the prior art and disparages prior art processes that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*;" (ii) repeatedly emphasizes that it is critical to guarantee the consistency of rifaximin crystalline forms and attributes, including in the summary of the invention, the

"surprising[]" properties of the invention to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*; (iii) depicts, in each figure and example, "[a] rifaximin polymorphic mixture of α/β form" that contains only the α and β rifaximin polymorphs; and (iv) does not disclose in any figure or example a rifaximin mixture that contains polymorphs other than α and β. ('099 Patent at 2:4–3:26 & 8:50–10:62 (emphasis added)). In other words, while there is a fine line between construing the claim in light of the specification and improperly importing limitations from the specification into the claim, the Court finds that construing "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" to mean "[a] rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs" is "required to tether the claims to what the specification[] indicate[s] the inventors actually invented." *Retractable Techs. Inc.*, 653 F.3d at 1305. As such, even though the claim language, which includes the terms "comprising," "comprises," and "mixture," leaves open the possibility that the disputed term may encompass additional rifaximin polymorphs, the Court finds that the specification here precludes such a possibility. And though Plaintiff contends that "the facially clear meaning" of this open-ended claim language cannot be changed by reliance "entirely on the specification" (Pl. Resp. Br. at 6), the Federal Circuit has emphasized that the specification "is *always* highly relevant to the claim construction analysis." *Phillips*, 415 F.3d at 1315 (emphasis added). Accordingly, rather than improperly reading a limitation from the specification into the claim, Defendants' construction, with which the Court agrees, properly reads the disputed claim term in the context of the entire patent. *See UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 823–24 (Fed. Cir. 2016) (finding that district court did not err in construing "handheld device" as "handheld *direct pointing* device" because even though a broader construction was plausible if the claim language was divorced from the specification, "the repeated description of

the invention as a direct-pointing system, the repeated extolling of the virtues of direct pointing, and the repeated criticism of indirect pointing" in the specification "clearly point[ed] to the conclusion that the 'handheld device'. . . . is limited to a direct-pointing device" (emphasis added)); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1148–50 (Fed. Cir. 2012) (concluding that the term "electrochemical sensor" did not include "external cables and wires connecting the sensor to its control unit," despite there having been no explicit disclaimer because the specification defined the term by implication and "contain[ed] only disparaging remarks with respect to the external cables and wires of the prior-art sensors" such that a construction including them would be inconsistent with the stated benefits of the invention); *see also In re Suitco*, 603 F.3d at 1260 (stating that the Board's construction of a claim reciting a "comprising" limitation must be "*consistent with the specification*" (internal quotation marks omitted)).

To be sure, the Federal Circuit has held that merely comparing and contrasting the present invention to that of the prior art is not sufficient to limit claim terms. *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019). However, here the specification of the '099 Patent does more than discuss certain disadvantages of prior art methods and is rather affirmatively limiting. The Federal Circuit's decision in *Cave Consulting Group, LLC v. OptumInsight, Inc.*, 725 F. App'x 988 (Fed. Cir. 2018) provides insight on this issue. In *Cave Consulting Group, LLC*, the Federal Circuit reviewed the construction of claim terms in a patent directed to "a method for measuring physician efficiency and patient health risk stratification," which included claim limitations for calculating "weighted episode of care statistics" to determine the physician's efficiency score. *Cave Consulting Grp., LLC*, 725 F. App'x at 989–90. The district court construed "weighted episode of care statistics" such that it included both indirect and direct standardization. *Id.* at 990. In finding that the district court erred in construing the claims to

include direct standardization, the Federal Circuit relied on the specification which consistently stated that the calculation of "weighted episode of care statistics" according to its method used indirect standardization and distinguished its method that used indirect standardization from the purportedly error-generating prior art methods that used direct standardization. *Id.* at 994. The court held that disclaimer through an explicit "clear and unmistakable" disavowal, in that case, was not necessary where the description itself was affirmatively limiting. *Id.* at 995. Further, though the court acknowledged that in general, statements about the difficulties and failures in the prior art, without more, do not limit claim terms, the court noted that in that case, the specification at issue did "more than discuss certain disadvantages of the prior art methods. It distinguishe[d] its invention from them, particularly pointing out what the invention d[id] not use." *Id.* Here too, the specification of the '099 Patent does more than discuss certain disadvantages of the prior art methods. Instead, it specifically distinguishes the present invention which includes an α/β rifaximin polymorphic mixture in a relative ratio of 85/15±3 that can be prepared *consistently*, from prior art methods that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." ('099 Patent at 2:23–28 & 3:3–13 (emphasis added)). As such, like in *Cave Consulting Group, LLC*, the specification of the '099 Patent is affirmatively limiting and indicates that Claim 1 does not encompass polymorphs other than the desired and consistently produced α/β polymorphs.

The prosecution history of the '099 Patent's parent, the '915 Patent, further confirms this understanding.[8] During prosecution of the '915 Patent, the applicant again emphasized the

[8] The Federal Circuit has explained that "[s]tatements made during prosecution of a parent application are relevant to construing terms" in a child patent "if such statements relate to the subject matter of the claims being construed." *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 933 F.3d 1345, 1350 (Fed. Cir. 2019); *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999) (applying statements from prosecution of a parent application where subject matter was common to the continuation-in-part application); *see also Jonsson v. Stanley Works*, 903 F.2d 812, 818 (Fed. Cir. 1990) (affirming claim construction relying on "arguments and remarks" made during the prosecution of a parent application for claim terms in a patent resulting from a continuation-in-part

importance of the consistency of the polymorphic form and criticized prior art methods that "produced the undesired γ polymorphic form or other polymorphic mixtures." ('915 Patent File History at 3–4). Further, at multiple points during prosecution, when distinguishing the present invention over U.S. Patent Number 8,067,429 to Gushurst to overcome an obviousness rejection, the applicant of the '915 Patent emphasized that it was the "specific ratio of α/β" claimed by the patent that "produced unexpected stability during physical treatments employed for the dry granulation and tableting." (*Id.* at 5 & 34). The applicant contrasted this to "[o]ther known polymorphs of rifaximin" that "may easily change their polymorphic form if exposed to different values of relative humidity." (*Id.*). Accordingly, the applicants' statements during prosecution of the '915 Patent, which emphasized the importance of the consistency of the polymorphic form and underscored that it was the specific ratio of α to β claimed by the invention that produced unexpected stability in contrast to other known polymorphs of rifaximin that could easily change their polymorphic form, indicate that the applicant intended to limit the claims to only the consistently produced α/β mixture, which did not contain any other undesired rifaximin polymorphs. In sum, when reading Claim 1 of the '099 Patent in light of the specification and prosecution history of its parent patent, the Court finds that the correct construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" is "A rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs."

application despite recognizing the claims used different language). Such is the case here. The '915 Patent and the '099 Patent have a familial relationship: The '915 Patent is the parent patent in the family, the '257 Patent is a continuation of the '915 Patent, and the '099 Patent is a divisional of the '257 Patent. (*See* '257 Patent Face Page; '099 Patent Face Page). Further, both patents share a substantively identical patent specification and contain claims commonly directed to α/β rifaximin polymorphic mixtures. (*See generally* '915 Patent & '099 Patent). As such, given the familial relationship and common subject matter, the Court finds that it can consider the prosecution history of the '915 Patent when construing Claim 1 of the '099 Patent. And at the *Markman* hearing, both parties agreed that it would be proper for the Court to consider the prosecution history of the '915 Patent when construing Claim 1 of the '099 Patent. (*See Markman* Hr'g Tr. at 37:5–20 & 38:8–13).

ii. The Court is not Convinced by Plaintiff's Contrary Arguments

Plaintiff's remaining arguments in opposition are not convincing. *First,* Plaintiff argues that the Court's claim construction decision in *Markman* Opinion I, which construed claim terms in the '915 Patent, '257 Patent, and '415 Patent, should not govern the construction of Claim 1 of the '099 Patent. (Pl. Resp. Br. at 4–6).[9] Plaintiff contends that while the claim language in the '099 Patent has some similarities to the previously construed claim terms in the '915 Patent, '257 Patent, and '415 Patent, Claim 1 of the '099 Patent also differs in a significant way because it includes the term "comprising" as the transitional phrase for the claimed tablet and also includes the term "comprises" as the transitional phrase in defining the claimed mixture. (*Id.* at 4). Plaintiff notes that the use of the second "comprises" term in Claim 1 of the '099 Patent as the transitional phrase in defining the claimed mixture is glaringly absent from any of the claims of the '915 Patent, '257 Patent, and '415 Patent that were previously construed. (*Id.* at 4–5). Plaintiff maintains that despite the intrinsic evidence that the Court considered in finding that the claims in the '915 Patent, '257 Patent, and '415 Patent should be construed as closed-ended, the inclusion of the claim term "comprises" as the transitional phrase defining the rifaximin polymorphic mixture unambiguously leads a POSA to interpret Claim 1 of the '099 Patent as open-ended. (*Id.* at 5).

The Court is not convinced. To be sure, as Plaintiff points out, unlike the claim terms this Court previously construed in the '915 Patent, '257 Patent, and '415 Patent, Claim 1 of the '099

[9] Plaintiff notes that in *Markman* Opinion I, the Court considered the possibility that the '915 Patent Family claim terms could be open-ended, but held that they were, in what the Court described as a "close" call, closed-ended due to other intrinsic evidence. (Pl. Open. Br. at 5). Here, Plaintiff contends that despite the intrinsic evidence that the Court considered in construing the other '915 Patent Family claims, the inclusion of the claim term "comprises" as the transitional phrase defining the rifaximin polymorphic mixture unambiguously leads a POSA to interpret the '099 Patent claims as open-ended. (*Id.*). To be sure, in *Markman* Opinion I, the Court noted that while it was close, the claim language in the '915 Patent, '257 Patent, and '415 Patent left open the possibility that the rifaximin polymorphic mixture of α/β form claimed in those patents may encompass additional rifaximin polymorphs. (*See, e.g..*, *Markman* Opinion I at 46). Nevertheless, the Court noted that the specifications of those patents "clearly preclude[d] such a possibility." (*Id.* at 54). The same is true here.

Patent includes the term "comprises" when defining the claimed rifaximin mixture, which is a term of art in patent law that means "including" or "including but not limited to." *Exergen Corp.*, 575 F.3d at 1319. Nevertheless, as stated above, the term "comprises" does not displace, or otherwise allow one to disregard, the patent specification. *Raytheon Co.*, 727 F. App'x at 672. Rather, the claims must be read in view of the specification, which "is always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." *Indacon*, 824 F.3d at 1355 (quoting *Phillips*, 415 F.3d at 1315) (internal quotation marks omitted). This fundamental precept is no less true for "comprising" claims than it is for other types of claims. *Raytheon Co.*, 727 F. App'x at 672; *see also In re Suitco*, 603 F.3d at 1260 (stating that the Board's construction of a claim reciting a "comprising" limitation must be "*consistent with the specification*" (internal quotation marks omitted)). And as described above, here the specification of the '099 Patent and the prosecution history of its parent patent—which distinguished the present invention that includes an α/β mixture in a relative ratio of 85/15±3 that can be prepared *consistently*, from prior art methods that did not result in the "*desired α or α/β mixtures*" of rifaximin but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*"—indicate that the correct construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs" is "A rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs." ('099 Patent at 2:23–28 & 3:3–13 (emphasis added); '915 Patent File History 3–5 & 34); *see Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 435 F. App'x. 927, 935 (Fed. Cir. 2011) (declining to construe a "pharmaceutical composition for injection" to cover any composition that includes a medicinal product, regardless of its suitability for injection into humans even where claim term recited "comprising" where "the addition of new compounds to the composition [] would defeat the 'pharmaceutical' character of

the overall composition [and] would move the composition outside the scope of the claimed invention"); *Lochner Techs., LLC v. Vizio, Inc.*, 567 F. App'x 931, 939–40 (Fed. Cir. 2014) ("After careful consideration, we find that the district court erred when it assumed that use of the term 'including' somehow trumped consideration of the specification and prosecution history and displaced application of standard claim construction principles. . . . In doing so, the court failed to properly consider the limiting language in the written description and the statements Lochner made over the course of the prosecution history.")[10]

Second, Plaintiff argues that the use of the word "relative" in Claim 1 of the '099 Patent compels an open-ended construction of the disputed claim term. (Pl. Open. Br. at 13). It asserts

[10] In its opening brief, Plaintiff appeared to argue that because the Federal Circuit has emphasized that under the doctrine of claim differentiation, different words or phrases used in different claims are presumed to indicate that the claims have different meanings in scope, the Court's claim construction decision in *Markman* Opinion I should not govern the construction of Claim 1 of the '099 Patent, which contains the distinct claim term "comprises" as the transitional phrase defining the rifaximin polymorphic mixture. (Pl. Open. Br. at 10–11). Though Plaintiff indicated at the *Markman* hearing that it did not intend to raise a claim differentiation argument to support its construction of Claim 1 of the '099 Patent (*Markman* Hr'g Tr. at 23:16–27:12), the Court finds that to the extent Plaintiff did intend to make a claim differentiation argument to support its construction, any such argument is unavailing.

The Federal Circuit has stated that the doctrine of claim differentiation is "not a hard and fast rule," but rather a presumption that will be overcome when the specification or prosecution history dictates a contrary construction. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005). And as described above, such is the case here. The Federal Circuit's decision in *Techtronic Industries Co. v. International Trade Commission*, 944 F.3d 901 (Fed. Cir. 2019) is instructive on this point. In *Techtronic*, the Federal Circuit considered the proper construction of claim terms in a patent directed to garage door opener technology, which included the claim limitation "wall console," and found that the patent at issue disavowed coverage of wall consoles lacking a passive infrared detector "because the specification, in each of its sections, disclose[d] as the invention a garage door opener improved by moving the passive infrared detector from the head unit to the wall console." *Techtronic*, 944 F.3d at 907. The commission argued that a broader construction was supported based on a theory of claim differentiation because claims of the parent patent were expressly directed to garage door openers that located the passive infrared detector in the wall console, indicating the patentee's intention to seek broader claims in the instant patent by not specifying the location of the passive infrared detector. *Id.* at 907. The Federal Circuit rejected this argument, noting that any presumption created by the doctrine of claim differentiation would be overcome by a contrary construction by the written description, and in that case, the fact that the patentee "obtained more modest claims in its parent patent d[id] not inoculate it from the specification's disavowal." *Id.* at 909. Likewise, here, the mere fact that the '099 Patent includes the term "comprises" in defining the claimed rifaximin polymorphic mixture, which does not appear in the '915 Patent, '257 Patent, or '415 Patent, does not inoculate the patentee from the affirmatively limiting statements in the specification of the '099 Patent. *See GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1371–72 (Fed. Cir. 2016) (rejecting plaintiff's argument that claim differentiation counseled against construing a "node" as a "pager" based on the fact that the parent patent specifically used the terms "paging system" and "paging unit" in its claims because claim differentiation is "not a hard and fast rule," but rather a presumption that will be overcome when the specification or prosecution history dictates a contrary construction).

that "relative" refers to the relation between the α and β rifaximin polymorphs, and the Claim's use of "relative ratio," to describe the percentages of α and β that must be present in the claimed rifaximin polymorphic mixture, would be redundant if polymorphic forms of rifaximin other than α and β had been excluded from the claims. (*Id.*). Plaintiff's argument is not persuasive and in fact, the Court rejected the same argument in *Markman* Opinion I. (*Markman* Opinion I at 47–48). As Plaintiff itself contends, the use of the word "relative" in Claim 1 of the '099 Patent simply appears to refer to the relationship between the α and β rifaximin polymorphs. Its use in the Claim does not necessarily become redundant if the Claim only covers the α and β rifaximin polymorphs because it still serves to describe the relationship between those two polymorphs. And regardless, claim terms must be read in view of the specification, and here, the specification of the '099 Patent undercuts Plaintiff's argument. The specification of the '099 Patent uses the term "relative ratio" even when describing rifaximin mixtures that clearly contain *only* the rifaximin α and β polymorphs. More specifically, when describing rifaximin mixtures that were used to create a calibration curve, the specification of the '099 Patent provides: "[t]he *relative ratio* between alpha and beta polymorphic forms were determined by DRX (powder) using a calibration curve obtained using two samples of Rifaximin prepared by mixing *pure alpha* (DRX: Enclosure 15) and *pure beta* (DRX: Enclosure 16) forms in a *relative ratio* of 80/20 and 90/10 (these samples were prepared according to EP1557421). The diagnostic diffraction peaks considered in order to quantify the *relative ratio* between the alpha and the beta form are the following . . ." ('099 Patent at 8:7–16 (emphasis added)). As this passage explains, the relevant samples at issue used to create the calibration curve were prepared by mixing pure rifaximin α and pure rifaximin β, resulting in a mixture that contains only the rifaximin α and β polymorphs. And the inventors use the word "relative" to describe the relationship between the α and β rifaximin polymorphs in this mixture

even though it does not contain any polymorphs other than rifaximin α and β. As such, this portion of the specification undercuts Plaintiff's argument that the Claim's use of the word "relative" compels an open-ended construction of the disputed claim term.

Third, Plaintiff argues that Defendants' construction is undercut by the fact that the specification discloses other rifaximin polymorphs. (Pl. Open. Br. at 13–14 (citing '099 Patent at 1:61–2:1)). Plaintiff points out that in the background of the invention, the specification of the '099 Patent states the following:

> Literature data confirm that [rifaximin] may be isolated in different crystalline forms identified with the letters of the Greek alphabet: the α, β and γ forms were disclosed on 2004 (EP1557421 by Alfa Wasserman), the ε and δ forms on 2006 (EP1698630 by Alfa Wasserman), the ζ, η, α dry, forms on 2009 (WO2009108730 by Salix Pharmaceuticals, Ltd.), κ and θ forms on 2011 (WO2011153444 by Salix Pharmaceuticals, Ltd.).

('099 Patent at 1:61–2:1). Further, Plaintiff points out that prior art cited on the face of the '099 Patent also discloses other polymorphic forms of rifaximin, further supporting an open-ended construction. (Pl. Open. Br. at 14 (citing D.E. No. 233-13, Ex. L, U.S. Patent No. 7,612,199 ("the '199 Patent") to Swift Decl. at Claims 1, 4 & 6 (disclosing rifaximin polymorphic forms α, β, and γ); D.E. No. 233-14, Ex. M, U.S. Patent No. 8,193,196 ("the '196 Patent") to Swift Decl. at Claim 1 (disclosing rifaximin polymorphic forms δ and ε); and D.E. No. 233-15, Ex. N, U.S. Patent No. 8,486,956 ("the '956 Patent") to Swift Decl. at Claims 1, 4 (disclosing rifaximin polymorphic forms ζ and ι))). These arguments are not convincing and in fact, the Court rejected similar arguments in *Markman* Opinion I. (*Markman* Opinion I at 60–61). Specifically, though the specification of the '099 Patent may in fact describe other polymorphic forms of rifaximin that have been disclosed in the prior art and cite to prior art that discloses other polymorphic forms of rifaximin, it goes on to explicitly disparage prior art processes that resulted in "the *undesired γ*

polymorphic form or other polymorphic mixtures" of rifaximin. ('099 Patent at 2:23–28 (emphasis added)). As such, Plaintiff's reliance on this background passage of the specification and prior art cited on the face of the '099 Patent is unavailing in light of the remainder of the intrinsic record, which indicates that other rifaximin polymorphs are not encompassed by the presently claimed invention. *See Symantec Corp.*, 811 F.3d at 1366 ("This single sentence in the specification cannot overcome the overwhelming evidence in other parts of the specification. . . demonstrating that the intended definition of this term does not include information other than machine code instructions. The patentee cannot rely on its own use of inconsistent and confusing language in the specification to support a broad claim construction which is otherwise foreclosed.").

Fourth, Plaintiff contends that its construction is supported by the fact that the '099 Patent specification includes both broad and narrower recitations of the invention. (Pl. Open. Br. at 14–15). Specifically, Plaintiff points out that in defining the claimed invention, the '099 Patent specification uses broad and open-ended terms, such as "mixture" when referring to the claimed invention stating, for example, that "[a]nother object of the present invention is a process for the preparation of said Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3." (*Id.* (citing '099 Patent at 3:27–29)). Plaintiff asserts that these broad statements are in stark contrast to other narrower statements in the specification that include language such as "can be prepared consistently solving the problems of the prior art" and "a *consistent* Rifaximin α/β mixture in a relative ratio of 85/15±3." (*Id.* at 15 (citing '099 Patent at 3:3–18 (emphasis added))). Plaintiff maintains this demonstrates that the repeated description of the invention with broad terms elsewhere in the specification and in the claims is meant to convey the open-ended nature of the claimed rifaximin mixture. (*Id.* at 15). The Court is not convinced.

To be sure, the specification of the '099 Patent does use the term "mixture" when referring to the claimed invention—which leaves open the possibility that the claimed rifaximin mixture may encompass additional unnamed ingredients. However, the remainder of the specification—which explains that the conversion between polymorphic forms of rifaximin was a problem in the prior art, repeatedly emphasizes that it is critical to guarantee the consistency of crystalline forms, disparages prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*," and attributes the "surprising[]" properties of the invention to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*—undercuts any such possibility. ('099 Patent at 2:13–51 & 3:3–6 (emphasis added)).

Fifth, though Plaintiff contends that Dr. Swift's declaration supports a construction of "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs," which does not exclude additional rifaximin polymorphs (Pl. Open. Br. at 17–18), the Court will not rely on extrinsic evidence in adopting a construction that is belied by the intrinsic evidence. *See, e.g.*, *Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history.'" (citation omitted)).

In sum, after considering claim context, the specification, and the prosecution history of the '099 Patent's parent and for all the foregoing reasons, the Court adopts Defendants' construction and construes "a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs," to mean "A rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs and no other Rifaximin polymorphs."

2. "[C]haracterized by an X-Ray spectrum with characteristic 2theta values" ('099 Patent, Claim 1)

Plaintiff	Defendants	The Court
Read in the context of the claim and specification as a whole, this phrase means: "characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92."	"having an X-ray spectrum with peaks at each of the recited 2theta values"	"having an X-ray spectrum with peaks at each of the recited 2theta values"

The disputed claim term "characterized by an X-Ray spectrum with characteristic 2theta values" appears in Claim 1 of the '099 Patent which reads as follows:

> 1: A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('099 Patent at 11:1–10). Plaintiff argues that the intrinsic and extrinsic record support a construction of the disputed claim term that means "characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92." (Pl. Open. Br. at 18). In contrast, Defendants contend that the intrinsic record supports a construction of "characterized by an X-Ray spectrum with characteristic 2theta values" that means "having an X-ray spectrum with peaks *at each of the recited 2theta values*." (Def. Open. Br. at 15 (emphasis added)). Accordingly, the parties' dispute centers around whether the claim language requires each and every one of the 18

recited 2theta values to be present to properly characterize the claimed rifaximin polymorphic mixture.[11] For the reasons set forth below, the Court adopts Defendants' construction.

i. The Intrinsic Record Supports Defendants' Construction

In resolving the parties' dispute, the Court begins, as it must, with the words of the claims. *Teleflex, Inc.*, 299 F.3d at 1324. Here, the claim language supports Defendants' construction. As set forth above, the plain language of Claim 1 of the '099 Patent indicates that the claimed α/β rifaximin polymorphic mixture is characterized by an X-ray spectrum of *18* specific peaks, or recited 2theta values. As Defendants point out (Def. Resp. Br. at 12), the patentee elected to claim the rifaximin polymorphic mixture by listing out 18 specific 2theta values; it "need not have included this limitation in its claims," but "[h]aving' done so, it must live with the language it chose." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1583 (Fed. Cir. 1996).

The Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) is instructive on this point. In *Glaxo*, the Federal Circuit provided guidance on how to assess claim limitations that characterize a composition by a set of specific peaks. There, the patents in suit characterized a crystalline form "by means of a specific, 29-peak infra-red (IR) spectrum." *Glaxo*, 110 F.3d at 1564. Additional dependent claims also defined the crystalline form as "characterized by a 32-intensity [X]-ray powder diffraction pattern." *Id.* The court found that establishing one of the claimed peaks was present in the accused products was "not sufficient to substitute for the claimed 29-peak spectrum." *Id.* at 1566. In so holding, the court explained that

[11] During the first round of claim construction, the parties disputed whether each of the 18 recited 2theta values appearing in similar claims in the '915 Patent, '415 Patent, and '257 Patent should be understood as "about" or absolute where the claims at issue did not explicitly recite the term "about" in modifying the recited 2theta values. (*Markman* Opinion I at 72–118). After reviewing the intrinsic and extrinsic evidence, the Court construed each of those values as "about" rather than absolute. (*Id.*). Claim 1 of the '099 Patent explicitly modifies each of the recited 2theta values with the term "about." ('099 Patent at 11:1–10). As such, whether each of those values should be understood as "about" or absolute is no longer at issue during this round of claim construction. Instead, the parties now dispute whether the claim language requires each and every one of the 18 recited 2theta values to be present to properly characterize the claimed rifaximin polymorphic mixture.

"[i]t is elementary patent law that all limitations are material. The single-peak analysis was thus insufficient because, as the district court correctly noted, in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims." *Id.* As such, the Federal Circuit concluded that the district court "did not clearly err in finding that Glaxo failed to demonstrate that the accused compositions would exhibit either the claimed characteristic IR or [X]-ray powder diffraction spectra of [the claimed composition], or in concluding that this failure was fatal to Glaxo's case." *Id.* Therefore, the Federal Circuit's analysis indicates that where a patentee claims a compound by reference to a set of peaks, each of those peaks constitutes an independent and material claim limitation that all must be present to show infringement.[12]

Other courts in this District have reached similar conclusions. For example, in *AstraZeneca AB v. Andrx Labs, LLC*, No. 14-8030, 2017 WL 111928 (D.N.J. Jan. 11, 2017), the court construed a claim which read as follows: "[t]he magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram" to mean "*having each of the referenced major peaks* in its X-ray powder diffractogram within normal experimental error." *Andrx*, 2017 WL 111928, at *6 & 47.[13] In reaching that conclusion, the court

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[12] The Federal Circuit's decision in *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) is also instructive in this case. In *Zenith*, the patent claimed a crystalline product "exhibiting essentially" a certain X-ray diffraction pattern having 37 lines. *Zenith*, 19 F.3d at 1420. The accused product was compared to a commercial product that exhibited only 30 of the 37 lines. *Id.* at 1424. The Federal Circuit noted "the term 'essentially' recited in the claim permits some leeway in the exactness of the comparison with the specified 37 lines of the claim term, [but] it does not permit ignoring a substantial number of lines altogether. *Id.* The court emphasized, that it "is the claim that sets the metes and bounds of the invention entitled to the protection of the patent system." *Id.* Accordingly, as the Federal Circuit later explained, "[i]n *Zenith*, the patentee's expert failed to verify that the reference sample exhibited *all* 37 lines of the x-ray diffraction pattern. Thus, even assuming the comparison was correct, the patentee failed to prove that all of the express limitations of the claim were satisfied." *Glaxo Grp. Ltd. v. TorPharm, Inc.*, 153 F.3d 1366, 1373 (Fed. Cir. 1998). And as stated above, relying on *Zenith*, the Federal Circuit in *Glaxo* noted that where a patentee claims a compound by reference to a set of peaks, each of those peaks constitutes an independent and material claim limitation that all must be present to show infringement. *Glaxo*, 110 F.3d at 1566. The same conclusion reached in *Glaxo* is warranted here.

[13] In *Andrx*, the court also declined to adopt a construction that would require each claimed peak to be absolute, particularly where the parties and their experts agreed "that there will be some range of normal experimental error in an X-ray powder diffractogram." *Andrx*, 2017 WL 111928, at * 48. As such, it adopted the construction: "having each of the referenced major peaks in its X-ray powder diffractogram *within normal experimental error*." *Id.* at *47–

noted that the patent applicants had elected to claim the compound by listing 13 major peaks of its XRPD. The court emphasized that the patentees had a variety of options when deciding how to characterize the compound of the claimed invention, "but chose to claim the compound in a certain way, and they must live with that choice." *Id.* Likewise, in *In re Sebela Patent Litigation*, the court declined to read certain infra-red peaks that were used to characterize the claimed compound out of the claim, emphasizing that "[a]lthough there may be multiple sets of correct peaks that can be selected to characterize a spectrum, a patentee who chooses to claim a compound using a particular set of 18 peaks, for whatever reasons, should be held to that list." No. 14-6414, 2017 WL 3449054, at *15 (D.N.J. Aug. 11, 2017); *see also Sebela Int'l Ltd. v. Actavis Lab'ys FL, Inc.*, No. 15-5308, 2016 WL 6871237, at *6 (D.N.J. Nov. 21, 2016) ("The inventors of the '271 patent had numerous ways of describing what they regarded as their invention. They chose to claim a crystalline form of paroxetine mesylate by reference to a set of IR peaks. The Court sees no reason to read the peaks out of the claim."); *Cephalon, Inc. v. Sun Pharm., Ltd.*, No. 11-5474, 2012 WL 12904999, at *10–11 (D.N.J. Dec. 20, 2012) (relying on *Glaxo* and treating individual XRPD peaks as claim limitations); *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 775 (N.D. Ill. 2007) ("Only four of these seven peaks are within . . . Claim 1. On that basis alone, the plaintiffs' claim of literal infringement fails, because in order for there to be literal infringement, each and every limitation of the claim must be met."). This case law supports Defendants' construction. As discussed in the above cited cases, the inventors of the '099 Patent had numerous ways of

48. As set forth above, in *Markman* Opinion I, the Court construed the recited 2theta values in claims of the related '915 Patent, '257 Patent, and '415 Patent as "about" rather than absolute, even where the patents did not explicitly modify those values by the term "about" in the claims in part because at the time of the invention, it was recognized that X-ray diffraction and the measurement of 2theta values involved some degree of experimental error. (*Markman* Opinion I at 72–118). As Defendants point out (Def. Resp. Br. at 8–9), here Claim 1 of the '099 Patent explicitly modifies each recited 2theta value with the term "about," indicating that some deviation from each value is permitted. (*See* '099 Patent at 11:1–10). As such, Defendants' proposed construction is consistent with *Markman* Opinion I and the court's broader holding in *Andrx*.

describing what they regarded as their invention. Yet, they decided to claim the α/β rifaximin polymorphic mixture by reference to *18* particular 2theta values. And "a patentee who chooses to claim a compound using a particular set of 18 peaks, for whatever reasons, should be held to that list." *In re Sebela*, 2017 WL 3449054, at *15. As such, claim context supports Defendants' construction.

Plaintiff argues that the phrases "characterized by" and "characteristic" as recited in Claim 1 of the '099 Patent are dispositive and dictate against Defendants' proposed construction that would always require each and every recited 2theta value. (Pl. Open. Br. at 19). Specifically, Plaintiff argues that the plain and ordinary meaning of "characterized by" and "characteristic" means to be able to identify something and does not require each and every recited 2theta value (*i.e.*, all 18 peaks) to be present to properly identify the claimed rifaximin polymorphic mixture. (*Id.*). To support its argument, Plaintiff cites to the court's decision in *Eisai Co. v. Glenmark Pharmaceuticals, Ltd.*, No. 13-1279, 2015 WL 1228958 (D. Del. March 17, 2015).

In *Eisai* the court construed the term "characterized by characteristic lines at" a specific set of "interplanar spacings (d values)." *Eisai*, 2015 WL 1228958, at *7. Though the parties disputed whether the term required every single recited d-value to be present in every experimental run, the court concluded that the plain and ordinary meaning of "'characterized by' d[id] not require all of the recited d-values to be present in every experimental run (*i.e.*, an exact one-to-one match)." *Id.* at *8. Rather, the court concluded that the broad claim language (drafted by the applicants and approved by the PTO) provided that the claim limitation is satisfied as long as the claimed crystal form can be "characterized by"—that is, *identified by*—reference to *the characteristic lines* set forth in the claim. *Id.* Noting that the claim language at issue in *Eisai* which used both "characterized by" and "characteristic" is highly analogous to the claim language at issue in this

case, Plaintiff contends that *Eisai* indicates that not all the peaks listed in Claim 1 of the '099 Patent need to be present. (Pl. Resp. Br. at 16).

In fact, Plaintiff contends that none of the cases cited by Defendants contain the claim language of the '099 Patent claims, with language that the compound is "*characterized by*" an X-ray diffraction pattern with "*characteristic*" 2theta values. (*Id.* at 14). For example, Plaintiff points out that while in *Glaxo*, the Federal Circuit considered a claim from U.S. Patent No. 4,521,431—which had the language "characterised by an infra-red spectrum . . . showing the following main peaks" in claim 1 and the language "characterised by the following [X]-ray powder diffraction pattern expressed in terms of 'd' spacings" in claim 2—neither of the claims in *Glaxo* included the "characteristic" language of the '099 Patent claims. (*Id.*). Plaintiff maintains the only case which examined the "characterized by" and "characteristic" claim language that is present in the '099 Patent claims is *Eisai*, which found that not all of the listed peaks need be present. (*Id.* at 16). Accordingly, Plaintiff argues that the phrases "characterized by" and "characteristic" as recited in Claim 1 of the '099 Patent are dispositive and dictate against Defendants' proposed construction that would always require each and every recited 2theta value. (Pl. Open. Br. at 19).

The Court is not convinced. "It is axiomatic that the claim construction process entails more than viewing the claim language in isolation." *See Retractable Techs., Inc.*, 653 F.3d at 1305. As such, Claim 1 of the '099 Patent must be read in view of the written description. *Phillips*, 415 F.3d at 1315. And here, the specification of the '099 Patent supports Defendants' construction and undercuts Plaintiff's arguments. Even if the plain and ordinary meaning of "characterized by" and "characteristic" is to be able to identify something as Plaintiff suggests (Pl. Open. Br. at 19), here the patentees of the '099 Patent specifically chose to "identify" the claimed α/β rifaximin polymorphic mixture by a set of *18* 2theta values, and as such should be held to that choice. Figure

4 of the '099 Patent, which embodies the subject matter of the invention, is illustrative of this point. Figure 4 of the '099 Patent, reproduced below, depicts the X-ray diffraction spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 87/13. ('099 Patent at 9:18–25).

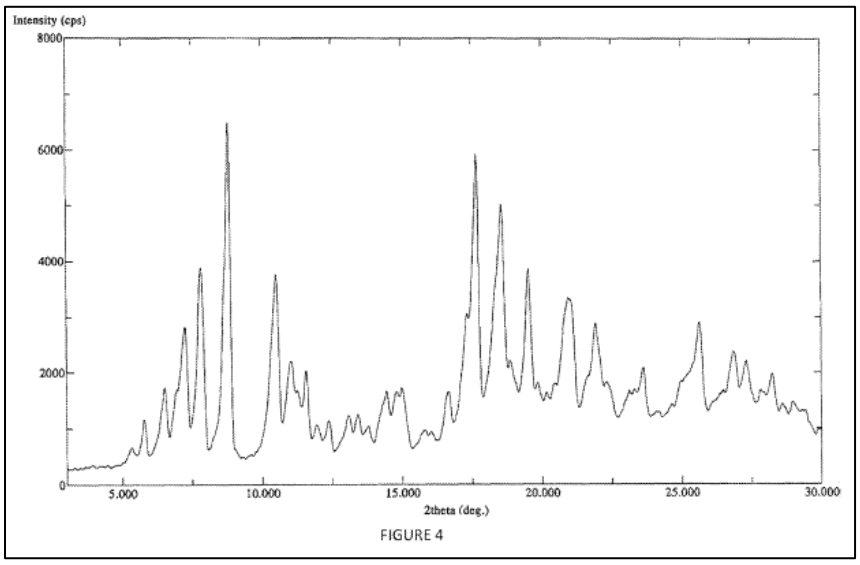

FIGURE 4

('099 Patent at Figure 4). The rifaximin composition embodied by Figure 4 is described in Example 2 of the '099 Patent. (*Id.* at 9:18–25). And Example 2 provides that "*the relevant peaks*"—that is, the peaks that are relevant in "identifying" the rifaximin α/β polymorphic mixture in a relative ratio of 87/13 depicted in Figure 4—correspond to the following 18 values, which are also recited in Claim 1 of the '099 Patent: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92. (*Id.* (emphasis added)). Elsewhere, the specification also characterizes the rifaximin α/β polymorphic mixture depicted in Figure 4 by the same 18 characteristic 2theta values. (*See id.* at 5:39–46). Yet, as both parties agreed, although the specification characterizes the rifaximin α/β polymorphic mixture depicted in Figure 4 by a set of 18 characteristic 2theta values, the diffractogram depicted in Figure 4 has significantly more than 18 peaks. (*Compare* '099 Patent at Figure 4, *with id.* at 9:18–25; Def. Resp. Br. at 12; *Markman* Hr'g Tr. at 52:12–15). As Defendants note (Def. Resp. Br. at 12), the

additional peaks depicted in Figure 4 could have been described in the specification and claimed. They were not. Instead, the patentees chose to "identify" or "characterize" the claimed α/β rifaximin polymorphic mixture by a subset of 18 "*relevant*" or "characteristic" peaks both in the specification and in Claim 1. ('099 Patent at 9:18–25 & 11:1–10). In fact, the specification at no point characterizes the rifaximin α/β polymorphic mixture of the claimed invention by anything other than a set of *18* "characteristic" 2theta values. (*See, e.g.*, '099 Patent at 5:39–46, 7:3–10,[14] 9:18–25). And as described above, consistent with the specification, the patentees elected to claim the α/β rifaximin polymorphic mixture by listing out 18 2theta values. Defendants' proposed construction, then, is gleaned directly from the specification of the '099 Patent.

In *Andrx*, the court addressed similar facts wherein the patentees had selected a subset of peaks to claim the invention and stated as follows:

> The Applicants elected to claim the compound of claim 1 by listing the 13 major peaks of its XRPD. The written description reveals that the XRPD depicted in [Figure] 1 included 'some additional very weak peaks,' however the Applicants chose to omit those additional very weak peaks in Table 1 and also in claim 1. The additional very weak peaks could have been shown in Table 1 and claimed. They were not. Based on AstraZeneca's arguments, some of the 13 claimed major peaks shown in Table 1 and claimed could have been

[14] As a note, the specification of the '099 Patent also describes the characteristic 2theta values that correspond to a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 that has been formed into uncoated tablets after being combined with excipients, which is depicted in Figure 5. ('099 Patent at 7:3–17 & 9:50–10:62). The specification likewise characterizes the X-ray spectrum corresponding to the rifaximin α/β polymorphic mixture itself in this tablet by a specific set of 18 characteristic 2theta values. (*Id.* at 7:3–10). Notably, the 18 2theta values that correspond to the rifaximin mixture that has been formed into tablets as depicted in Figure 5 are slightly different than the 18 2theta values that correspond to the rifaximin mixture depicted in Figure 4, which depicts the X-ray diffraction spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 87/13 only, with *no excipients*. (*Compare* '099 Patent at 7:3–10 (reciting, for Figure 5, 18 2theta values for the rifaximin mixture itself of 5.28, 5.78, 6.52, 7.26, 7.88, 8.82, 10.52, 11.02, 11.58, 13.12, 14.48, 17.38, 17.72, 18.62, 19.54, 21.10, 21.64, 22.00), *with id.* at 9:18–25 (reciting, for Figure 4, 18 2theta values for the rifaximin mixture of 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, 21.92)). Nevertheless, as explained above, Claim 1 of the '099 Patent explicitly recites the word "about" to modify each of the recited 2theta values, indicating that some deviation from each value is permitted. ('099 Patent at 11:1–10). And even though the 2theta values that correspond to the rifaximin polymorphic mixture itself depicted in Figure 5 are slightly different than the 2theta values that correspond to the rifaximin mixture depicted in Figure 4, the specification still uses a set of 18 2theta values to characterize both rifaximin mixtures, indicating that 18 2theta values (and not a different set of values) are significant in characterizing the rifaximin α/β polymorphic mixture of the claimed invention.

> omitted. However, they were not . . . The Applicants had a variety of options, but chose to claim the compound in a certain way, and they must live with that choice.

Andrx, 2017 WL 111928, at *47.[15] As described above, the same conclusion is warranted in this case with respect to Claim 1 of the '099 Patent. Specifically, though the patentees had a variety of options in choosing how to "identify" the claimed α/β rifaximin polymorphic mixture, they took care to characterize the compound with reference to a subset of *18* "relevant" or "characteristic" peaks both in the specification and in the disputed claim, and they must live with that choice. *Id.*; *Zenith*, 19 F.3d at 1424 ("It is the claim that sets the metes and bounds of the invention entitled to the protection of the patent system.").

As set forth above, Plaintiff contends that *Eisai* is the only case which examined the "characterized by" and "characteristic" claim language that is present in the '099 Patent claims and in *Eisai* the court found that not all of the listed peaks need be present. (Pl. Resp. Br. at 16); *Eisai*, 2015 WL 1228958, at *7–8. Accordingly, Plaintiff maintains that *Eisai* compels the conclusion that their construction is correct. (Pl. Resp. Br. at 16). Here, as stated above, though

[15] As stated, in *Andrx* the court construed a claim which read as follows: "[t]he magnesium salt of S-omeprazole trihydrate, wherein the compound ***is*** *characterized by* the following major peaks in its X-ray diffractogram" to mean "*having each of the referenced major peaks* in its X-ray powder diffractogram within normal experimental error," notwithstanding the use of "characterized by" in the claims. *Andrx*, 2017 WL 111928, at *6, *47–48 (emphasis added). Plaintiff points out that in *AstraZeneca AB v. Dr. Reddy's Laboratories, Inc.*, No. 11-2317, 2013 WL 1847639 (D.N.J. May 1, 2013) the court rejected construing *"characterized by* the following major peaks in its X-ray diffractogram"—the same claim term at issue in *Andrx*—as "having all of the referenced major peaks in its X-ray diffractogram" because the proposed construction "would require an exact match, [which] is too rigid," and "[t]he claim language require[d] only that [the drug] be 'characterized' by the peaks in the table, not necessarily that it have a perfect one-to-one relationship." (Pl. Resp. Br. at 16 (citing *Dr. Reddy's*, 2013 WL 1847639, at *8–9)). Plaintiff contends that the court's decision in *Dr. Reddy's* is more persuasive than the court's decision in *Andrx*. (*Id.*). Plaintiff's argument is not convincing. In *Andrx*, the court noted that its construction was not inconsistent with the construction in *Dr. Reddy's*. *Andrx*, 2017 WL 111928, at *48. The court noted that in *Dr. Reddy's*, Judge Pisano rejected the defendants' proposed construction ("having all of the referenced major peaks in its X-ray diffractogram") as too rigid, noting it failed to account for experimental error. *Id.* However, the *Andrx* court noted that in *Dr. Reddy's* Judge Pisano did not construe the term to include less than all of the recited 13 major peaks. Instead, he held that a perfect one-to-one relationship was not required because "the positions for the peaks may differ somewhat because of slight experimental errors." *Id.* The *Andrx* court noted that its construction, which accounted for normal experimental error, satisfactorily addressed Judge Pisano's concerns in *Dr. Reddy's*. *Id.* As such, Plaintiff's reliance on *Dr. Reddy's* does not lead this Court to reach a contrary conclusion.

Claim 1 of the '099 Patent does in fact recite the terms "characterized by" and "characteristic" in defining the claimed invention, that language must receive consideration in the context of the remainder of the intrinsic record, including the specification, which "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). And as stated above, here, the specification indicates that though the patentees had a variety of options in choosing how to "identify" the claimed α/β rifaximin polymorphic mixture, they chose to characterize the compound with reference to a subset of *18* "relevant" or "characteristic" peaks both in the specification and in the claims, and they must live with that choice. *See Andrx*, 2017 WL 111928, at *47; (*see also, e.g.*, '099 Patent at Figure 4, 5:39–46 & 9:18–25). In other words, the specification indicates that the terms "characterized by" and "characteristic" in Claim 1 of the '099 Patent are simply meant to emphasize that while there are other ways in which the patentees could have chosen to "identify" the claimed α/β rifaximin polymorphic mixture, the 18 listed 2theta values are the ones the patentees took care to identify as "characteristic" of the claimed invention. *Cf. Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-0905, 2018 WL 4776372, at *12 (D. Del. June 18, 2018) ("[T]he word 'main' in the claim is simply meant to emphasize that while there are other peaks in the full x-ray diffractograms for both of the crystalline forms, the listed peaks are the ones the patentee took care to identify as those characterizing the two crystalline forms that are the invention."); (*see also Markman* Hr'g Tr. at 64:17–65:4). As such, the Court declines to read the peaks out of the claim.

Further, as set forth above, the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) undercuts Plaintiff's argument. In *Glaxo*, the patents in suit "characterize[d]" a crystalline form "by means of a specific, 29-peak infra-red (IR) spectrum."

Glaxo, 110 F.3d at 1564. Additional dependent claims also defined the crystalline form as "characterized by a 32-intensity [X]-ray powder diffraction pattern." *Id.* Notwithstanding the patentee's use of claim language analogous to the claim language at issue in Claim 1 of the '099 Patent, the Federal Circuit concluded that where a patentee claims a compound by reference to a set of peaks, each of those peaks constitutes an independent and material claim limitation that all need to be present to demonstrate infringement. *Id.* at 1566.[16] As such, the claim language and the specification support Defendants' construction and the Court will not rely on *Eisai* in reaching a contrary conclusion.

The prosecution history provides added support for Defendants' construction. As stated above, the prosecution history "may be critical in interpreting disputed claim terms because it 'contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims.'" *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) (quoting *Vitronics*, 90 F.3d at 1582). Accordingly, even where "prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction." *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1366 (Fed. Cir. 2015). Here, the prosecution history of the '099 Patent informs the Court's construction of the disputed claim term. During prosecution

[16] As set forth above, Plaintiff maintains that *Glaxo* is distinguishable because the claims at issue in that case did not include the "characteristic" language of the '099 Patent claims. (Pl. Resp. Br. at 14). The Court is not convinced. At bottom, the Federal Circuit in *Glaxo* emphasized that where a patentee claims a compound by reference to a set of peaks, each of those peaks constitutes an independent and material claim limitation that all need to be present to demonstrate infringement. *Glaxo*, 110 F.3d at 1566. In fact, the Federal Circuit concluded that the district court "did not clearly err in finding that Glaxo failed to demonstrate that the accused compositions would exhibit either the claimed *characteristic* IR or [X]-ray powder diffraction spectra of [the claimed composition], or in concluding that this failure was fatal to Glaxo's case." *Id.* The same conclusion is warranted here. Further as explained above, the specification indicates that the term "characteristic" in Claim 1 of the '099 Patent is simply meant to emphasize that while there are other ways in which the patentees could have chosen to "identify" the claimed α/β rifaximin polymorphic mixture, the 18 listed 2theta values are the ones the patentees took care to identify as those characterizing the claimed invention. (*See Markman* Hr'g Tr. at 64:17–65:4). As such, the Court declines to read the peaks out of the claim.

of the '099 Patent, the applicant initially amended then pending Claims 33 and 34 to recite the below (presented in 'clean' form):

> 33. A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15 ± 3.
>
> 34. The tablet of claim 33, wherein the Rifaximin polymorphic mixture is characterized by an X-ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

(D.E. No. 234-7, Ex. 6 to Weisbruch Decl. at 2). Subsequently, the Examiner rejected then-pending Claim 33 as obvious over three prior art references. (*See* D.E. No. 234-8, Ex. 7 to Weisbruch Decl. at 4). And as to Claim 34, the Examiner stated that it would be allowable if rewritten as an independent, rather than dependent claim, "including all of the limitations of the base claim and any intervening claims." (*Id.* at 2). In response, the applicant canceled Claim 34 and incorporated the limitations from Claim 34 into Claim 33—which issued as the current version of Claim 1 of the '099 Patent—as shown below:

> 33. (Currently Amended) A tablet obtained by a dry granulation and tableting procedure comprising a Rifaximin polymorphic mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3, wherein the Rifaximin polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

(D.E. No. 234-9, Ex. 8 to Weisbruch Decl. at 2). After the amendment, the Examiner explained the claims were allowed because the prior art did not "specifically teach a Rifaximin polymorphic mixture of α/β form . . . characterized by an X-ray spectrum with characteristic 2theta values as recited" in Claim 33. (D.E. No. 234-10, Ex. 9 to Weisbruch Decl. at 2)). The Examiner went on

to state: "*These are specific peaks that are not disclosed in [the prior art references].*" (*Id.* (emphasis added)).

Though the Federal Circuit has held that an Examiner's Statements of Reasons for Allowance "will not necessarily limit a claim," it does not necessarily follow that such statements are not pertinent to construing claim terms, especially when amendments to the claims prompted the Examiner's statements. *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003); *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005). In fact, "[s]tatements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed." *Salazar*, 414 F.3d at 1347. As Defendants point out (Def. Open. Br. at 17–18), the fact that a specific set of *18* 2theta values were added into the current version of Claim 1 by the patentees of the '099 Patent to overcome the prior art—at the direction of the Examiner—and expressly identified by the Examiner as the "*specific peaks*" that were not disclosed in the prior art and thereby able to successfully overcome the prior art rejections, reinforces the conclusion that the claim is properly construed as "having an X-ray spectrum with peaks *at each of the recited 2theta values*." *See, e.g.*, *SandBox Logistics LLC v. Proppant Express Invs. LLC*, 813 F. App'x 548, 554–55 (Fed. Cir. 2020) (upholding the district court's construction of the term "bottom" in a family of patents related to systems for using proppant at a well site to mean "bottom wall" and relying on the prosecution history of the parent patent, including the Examiner's Statement of Reasons for Allowance, which indicated that the Examiner allowed the patent based in part on his understanding that the claims were amended to include a bottom wall); *Koepnick Med. & Educ. Rsch. Found., L.L.C. v. Alcon Lab'ys, Inc.*, 162 F. App'x 967, 971–72 (Fed. Cir. 2005) ("The prosecution history further confirms the district court's construction of 'excising' as 'cutting out.'

The PTO examiner asserted in the Notice of Allowance of the '303 patent that 'the primary reason for allowance is that the prior art of record fails to teach or adequately disclose the steps of *cutting two disks from* the eye.'"); *TorPharm, Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003) ("[I]n ascertaining the scope of an issued patent, the public is entitled to equate an inventor's acquiescence to the examiner's narrow view of patentable subject matter with abandonment of the rest. Such acquiescence may be found where the patentee narrows his or her claims by amendment[.]" (internal citation omitted)).

ii. The Court is not Convinced by Plaintiff's Contrary Arguments

Plaintiff's remaining arguments in opposition are not convincing. *First,* Plaintiff argues that its construction is supported by the specification. Specifically, Plaintiff points out that the specification clarifies that a POSA need not consider all values disclosed in the patent as absolute as long as the "technical effect" of the invention is achieved as follows:

> It is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value or interval must be understood by the person of ordinary skill in the art as 'about'. The term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved.

(Pl. Open. Br. at 19–20 (citing '099 Patent at 4:62–5:3)). Plaintiff contends this passage supports its argument that Claim 1 of the '099 Patent should not be construed as Defendants propose, but rather that some of the recited 2theta values can be missing or not shown as long as the "technical effect of the '099 Patent" can be achieved. (*Id.* at 19–20). This argument is unavailing. As Defendants point out (Def. Resp. Br. at 14), this passage only teaches that the values in the '099 Patent, *i.e.*, the recited 2theta values, should be understood as "about" rather than absolute. In fact, in *Markman* Opinion I, the Court relied on this passage to support its finding that the term "about"

should be read into the claims of the '915 Patent, '257 Patent, and '415 Patent to modify the 2theta values recited therein where the claims did not explicitly modify the recited values with the term "about." (*See Markman* Opinion I at 75–77). Here, Claim 1 of the '099 Patent expressly incorporates "about" into the claim with respect to the 2theta values. ('099 Patent at 11:1–10 ("characterized by an X-Ray spectrum with characteristic 2theta values *at about*: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92" (emphasis added))). In other words, the teaching of this passage from the specification, which provides that the values in the patent, *i.e.*, the recited 2theta values, should be understood as "about" rather than absolute, is already incorporated into the language of Claim 1. And while this passage provides that deviations from the recited 2theta values are permitted, it does not state or suggest that any of the claimed 2theta values can be ignored altogether, as Plaintiff contends. As Defendants point out, "[s]pecifying a deviation or margin of error for a value does not imply that the value can be disregarded entirely, only that some deviation from the value is permitted." (Def. Resp. Br. at 14). Accordingly, Plaintiff's argument is unavailing.

Second, Plaintiff contends that patents cited on the face of the '099 Patent support its proposed construction. (Pl. Open. Br. at 23–24). For example, it points out that the '199 Patent, cited on the face of the '099 Patent, is directed to polymorphic forms of rifaximin and characterizes both the α and β polymorphic forms of rifaximin with only seven (7) total 2theta peaks rather than 18 peaks. (*Id.* at 24 (citing '199 Patent at Claim 1 (requiring four diffraction peaks at about 7.4°; 19.7°; 21.0° and 22.1° 2theta to characterize rifaximin polymorph α); *id.* at Claim 4 (requiring three diffraction peaks at about 5.4°; 9.0°; and 20.9° 2theta to characterize rifaximin polymorph β))). Plaintiff asserts that a POSA would understand from this disclosure that a mixture of α and β rifaximin polymorphs can be "identified" or "characterized" from less than the 18 peaks recited

in Claim 1 of the '099 Patent. (*Id.*). The Court is not convinced. As Defendants argue (Def. Resp. Br. at 16), though certain of Defendants' patents may disclose that the α and β polymorphic forms of rifaximin can be identified by less than 18 peaks, here the patentees of the '099 Patent chose to identify their α/β rifaximin polymorphic mixture using a specific set of 18 peaks. Having chosen to so claim their invention, they must live with that choice. *Andrx*, 2017 WL 111928, at *47.

Third, Plaintiff contends that extrinsic evidence supports its construction. To start, Plaintiff cites Dr. Swift who states that Plaintiff's construction is consistent with how a POSA would have understood the meaning of the claim considering the '099 Patent as a whole at the relevant time period. (Pl. Open. Br. at 21 (citing Swift Decl. ¶¶ 64–79)). Specifically, Dr. Swift explains that, when trying to characterize the polymorphic composition of a crystalline form using X-ray diffraction, a POSA would recognize that, due to various experimental factors, not all known 2theta values may be detected during every experimental run. (*Id.* (citing Swift Decl. ¶ 72); Pl. Resp. Br. at 18). Dr. Swift states that a POSA would have looked to the United States Pharmacopeia ("USP") 941 as an authoritative guide to understand X-ray diffraction readings. Plaintiff points out that USP 941 discloses that "[t]he identification of the phase composition of an unknown sample by XRPD is usually based on the visual or computer-assisted comparison of a portion of its X-ray powder pattern to the experimental or calculated pattern of a reference material." (Pl. Open Br. at 21 (citing USP 941 at 507 & Swift. Decl. ¶¶ 71–72)). Plaintiff proposes that the construction of the "characterized by" term be consistent with how a POSA would confirm whether a claimed polymorphic mixture in a specific ratio is present or absent—that is, a POSA would review the X-ray diffraction pattern of an unknown sample as a whole, referencing the recited diffraction values of a known sample, and conduct a computer-assisted comparison to confirm the presence or absence of the claimed subject matter (here, a Rifaximin polymorphic

mixture that comprises α and β Rifaximin polymorphs in a α/β relative ratio of 85/15±3). (*Id.* at 23). Plaintiff states that a POSA would not need to "see" all of the recited peaks to make this determination. (*Id.*). Further, Plaintiff asserts that as of the priority date of the '099 Patent, a POSA would have been well aware of what is referred to as "background" in X-ray diffraction experimental readings, which consists of X-ray scattering caused by something other than the sample at issue. (*Id.* at 21). Plaintiff explains that the X-ray diffraction equipment itself contributes to background, as well as excipients in the drug product, specimen preparation, the "sample holder, diffuse scattering from air and equipment, and other instrumental parameters such as detector noise and general radiation from the X-ray tube." (*Id.* at 21–22 (citing USP 941 at 504 & Swift Dec. ¶¶ 73 & 76)). Plaintiff asserts that a POSA would know that the background from any of these sources could superimpose with certain diffraction peaks (2theta values) that correspond to the claimed rifaximin mixture and cause them to be undetected. (*Id.* at 22). In fact, at her deposition, Dr. Swift testified that based on her own personal expertise looking at many thousands of powder X-ray diffraction patterns, not all 2theta values, or peaks, are present after every experimental run for a variety of reasons, further supporting Plaintiff's construction. (Pl. Resp. Br. at 12–13 (citing D.E. No. 237-3 at 15:17–21 & 73:4–75:24)). Therefore, given the realities of X-ray diffraction technology, Plaintiff claims that a POSA would not interpret the claim to be so rigid as to require every one of the 18 2theta values to characterize the invention. (Pl. Open. Br. at 21).

The Court will not alter its conclusion based on Plaintiff's reliance on this extrinsic evidence. As Defendants contend (Def. Resp. Br. at 16), where the intrinsic record unambiguously describes the scope of the patented invention, as it does here, reliance on any extrinsic evidence to support a contrary construction is improper. *See Pitney Bowes, Inc.*, 182 F.3d at 1308 (citing

Vitronics, 90 F.3d at 1583). And regardless, as Defendants note, the extrinsic evidence Plaintiff cites to focuses on the question of infringement, and not the meaning and scope of the claim. (Def. Resp. Br. at 16–17). Specifically, as discussed above, much of Plaintiff's briefing with respect to this claim term focuses on how a POSA would compare a diffractogram for a tested compound to a reference diffractogram to determine whether there is a match for purposes of infringement. (*See, e.g.*, Pl. Open. Br. at 23 ("[Plaintiff] proposes that the construction of the 'characterized by' term be consistent with how a POSA would confirm whether a claimed polymorphic mixture in a specific ratio is present or absent—that is, a POSA would review the X-Ray diffraction pattern as a whole, referencing the recited diffraction values, and conduct a computer-assisted comparison to confirm the presence or absence of the claimed subject matter."); *id.* at 21–22 ("A POSA would know that the background . . . could superimpose with certain diffraction peaks and cause them to be undetected.")).

However, at this stage, the Court is not focused on evaluating the difficulties a POSA may face in comparing a diffractogram for a tested compound to a reference diffractogram to determine whether there is a match based on various experimental factors. Rather the Court's concern at this stage is defining the proper meaning and scope of this claim term. The court in *Andrx* dealt with a similar issue. Specifically, there the plaintiff argued that the claim term "characterized by the following major peaks in its X-ray diffractogram" need not contain every listed peak, in part because (i) a POSA "would recognize that while the [claimed compound] at issue should be 'identifiable by reference' to a diffractogram including the listed peaks, an infringing [compound] need not necessarily contain all of the listed peaks;" and (ii) "Peaks from other components in [a drug] product, such as excipients, may interfere with the peaks attributable to the compound." *Andrx*, 2017 WL 111928, at *48. The court rejected those arguments because they improperly

focused on the question of infringement and not the meaning and scope of the claim. *Id.* The same conclusion is warranted here. As Defendants maintain (Def. Resp. Br. at 17), this Court's claim construction should not be influenced by extrinsic evidence that indicates infringement may be difficult to prove in some circumstances. *See Sebela*, 2017 WL 3449054, at *15 ("Plaintiff suggests . . . that holding a patentee to a particular list of peaks would be improper in light of scientific realities. Logic dictates otherwise. Although there may be multiple sets of correct peaks that can be selected to characterize a spectrum, a patentee who chooses to claim a compound using a particular set of 18 peaks, for whatever reasons, should be held to that list."); *see also Cephalon*, 2012 WL 12904999, at *11 ("Cephalon argues that not all nine peaks need to be identified in order to find infringement, and that, as a 'matter of science,' the Court can infer the presence of the remaining peaks. The Court is aware of no authority supporting this proposition, which runs counter to the Federal Circuit's requirement that a finding of literal infringement requires the presence of each and every claim limitation in the alleged infringing product." (citing *Glaxo*, 110 F.3d at 1566)).

In a similar vein, Plaintiff also argues that Defendants' proposed construction ignores the knowledge of a POSA. (Pl. Open. Br. at 22–23). To illustrate this point, Plaintiff points to a portion of the specification that describes Figure 5 of the '099 Patent. Figure 5 depicts the X-ray spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 that has been formed into uncoated tablets, after being combined with different excipients. ('099 Patent at 7:3–18 & 9:50–10:62). And the specification again characterizes the X-ray spectrum corresponding to the rifaximin α/β polymorphic mixture itself depicted in Figure 5 by reference to 18 2theta values. (*Id.* at 7:3–10). The specification then also discloses the diagnostic 2theta values that correspond to the excipients that have been added to the rifaximin α/β polymorphic mixture of Figure 5, to

form uncoated tablets as follows: "[t]he following diagnostic peaks of the employed excipients are also detectable on the DRX spectrum . . . 19.10[] and 28.72[] for talc; 22.36[] microcrystalline cellulose; 21.10[] for glycerol palmitostearate; 45.74[] sodium starch glycolate; hydrate silicon dioxide is amorphous and does not present diffraction peaks." (*Id.* at 7:10–18). Plaintiff points out that some of these excipients have diffraction peaks that are very close in value with the claimed characteristic 2theta values corresponding to the rifaximin polymorphic mixture itself. (Pl. Open. Br. at 23). Plaintiff asserts that a POSA would understand that the overlapping peaks (*e.g.*, 21.10 2theta for glycerol palmitostearate (an excipient) and 21.04 2theta for the rifaximin mixture in claim 1) or adjacent peaks (*e.g.*, 22.36 2theta for microcrystalline cellulose (an excipient) and 21.92 2theta for the rifaximin mixture in claim 1) could alter the background upon which the peaks are superimposed, and as a result, potentially change the characteristic 2theta values of the claimed rifaximin mixture, which may also lead to some of the diffraction peaks not being detected. (*Id.*).

The Court is not convinced. Even though some of the 2theta values corresponding to the excipients of the mixture depicted in Figure 5 may in fact be very close in value to the 2theta values that correspond to the rifaximin polymorphic mixture itself, the patentee still took care to characterize the X-ray spectrum corresponding to the rifaximin α/β polymorphic mixture itself depicted in Figure 5 by a set of ***18*** specific 2theta values. ('099 Patent at 7:3–10). And again, having chosen to so characterize their invention, the patentees must live with that choice. *Andrx*, 2017 WL 111928, at *47. Further as stated above, though the presence of excipients in a given mixture may make it more difficult for a POSA to determine whether other 2theta peaks corresponding to the rifaximin polymorphic mixture itself appear in any given experimental run, such concerns go to the question of infringement, rather than the proper scope and meaning of the

claim. *Andrx*, 2017 WL 111928, at *48 (rejecting plaintiff's argument that claim term "characterized by the following major peaks in its X-ray diffractogram" need not contain every listed peak based on the fact that "[p]eaks from other components in [a drug] product, such as excipients, may interfere with the peaks attributable to the compound," because such arguments improperly focused on the question of infringement and not the meaning and scope of the claim.). As such, the Court finds Plaintiff's argument unavailing.

Finally, Plaintiff contends that even though the terms "characterized by" and "characteristic" were present in the claims of the '915 Patent, '415 Patent, and '257 Patent, which this Court previously held *Markman* proceedings for, Defendants did not raise any need to construe such terms in those patents even though the language is substantially the same in Claim 1 of the '099 Patent. (Pl. Open. Br. at 20 n.3). Plaintiff contends that Defendants' failure to previously raise this during the first round of claim construction should operate as a waiver. (*Id.*). In response, Defendants argue that they are aware of no authority, and Plaintiff has cited none, which stands for the proposition that claim construction arguments are waived if not presented at the *Markman* stage of a case. (Def. Resp. Br. at 17). They state this is particularly true where, as here, the patent whose construction is at issue was not asserted in this consolidated litigation until four months *after* the original *Markman* hearing. (*Id.*). Defendants also contend that it is well established that claim construction can occur during various phases of a litigation, including after expert discovery or even at trial, when it becomes apparent that the parties have an unresolved dispute over the proper construction of an asserted claim. (*Id.* at 18). Here, Defendants state that the dispute over the proper construction of this term only became apparent *after* Plaintiff produced test data on Defendants' accused XIFAXAN® tablets in January and July of 2023, after *Markman* briefing on the '915 Patent, '257 Patent, and '415 Patent was complete. (*Id.*). Defendants analyzed the data

and discovered that Plaintiff's X-ray diffractograms do not show the presence of each of the recited 2theta values of Claim 1 of the '099 Patent. Hence the dispute. (*Id.*). For the following reasons, the Court declines to find a waiver.

The Federal Circuit has recognized that "district courts may engage in a rolling claim construction." *See Pressure Products Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1316 (Fed. Cir. 2010). And "[w]hen the parties raise an actual dispute regarding the proper scope of the[] claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). To the extent a party *can* be deemed to have waived claim construction-related concerns, courts have discretion regarding whether to find a party waived their opportunity to raise such concerns. *See, e.g.*, *Cioffi v. Google, Inc.*, No. 13-0103, 2017 WL 275386, at *5 n.2 (E.D. Tex. Jan. 9, 2017). Federal Circuit precedent indicates that waiver generally arises where (i) a party fails to object to jury instructions using a certain claim construction; (ii) raises claim construction disputes for the first time after trial; (iii) engages in clear conduct showing acquiescence to a particular claim construction (*e.g.*, withdrawing prior objections before later attempting to re-assert them), or (iv) fails to preserve the issue at the district court level altogether. *Daedalus Blue, LLC v. MicroStrategy Inc.*, No. 20-0551, 2023 WL 5941736, at *13 (E.D. Va. Sept. 12, 2023) (citing *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1003–04 (Fed. Cir. 2014); *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1408 (Fed. Cir. 2004); *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1262 (Fed. Cir. 2013); *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009); and *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 694 (Fed. Cir. 2008)).

Waiver is not appropriate here. As an initial matter, Plaintiff did not initiate the Second Action asserting the '099 Patent—whose construction is now at issue—against Defendants until

August of 2023, four months *after* the original *Markman* hearing took place in the First Action on April 27, 2023. (*See* Second Compl.; D.E. No. 135). In fact, the Second Action asserting the '099 Patent was not consolidated with the First Action until September 27, 2023. (D.E. No. 170). Further, based on Defendants' assertions, it appears that the proper construction of "characterized by an X-Ray spectrum with characteristic 2theta values" only became apparent in January and July of 2023 after the first round of *Markman* briefing was complete when Plaintiff produced test data on Defendants' accused XIFAXAN® tablets and Defendants analyzed that data. (Def. Resp. Br. at 17; *see also Markman* Hr'g Tr. at 90:6–18). And "[w]hen the parties raise an actual dispute regarding the proper scope of the[] claims, the court, not the jury, must resolve that dispute." *O2 Micro*, 521 F.3d at 1360. Further, none of the circumstances outlined above, which have prompted a finding of waiver, are present in this case. *See Daedalus Blue, LLC*, 2023 WL 5941736, at *13. As such, the Court declines to find a waiver.

In sum, after considering claim context, the specification, and the prosecution history and for all the foregoing reasons, the Court adopts Defendants' construction and construes "characterized by an X-Ray spectrum with characteristic 2theta values" to mean "having an X-ray spectrum with peaks at each of the recited 2theta values."

IV. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.

Dated: September 4, 2024

s/ Esther Salas
Esther Salas, U.S.D.J.